वार्षिक बुलेटिन-२०८२

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

राष्ट्रिय औषधि प्रयोगशाला

बिजुलीबजार, काठमाडौँ

National Medicines Laboratory key activities

- Testing and analysis of drugs as mandated by Drugs Act, 1978.
- Analytical method validation of Non-Pharmacopoeia products.
- GLP audit of pharmaceutical QC laboratories and private laboratories
- Proficiency testing
- Lot release of biological products

वार्षिक बुलेटिन - २०८२

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

राष्ट्रिय औषधि प्रयोगशाला

बिजुलीबजार, काठमाडौँ

info@nml.gov.np, Contact no. 4781269

सम्पादक मण्डल

सम्पादकीय

औषधि ऐन, २०३५ को दफा ६ बमोजिम स्थापना भएको नेपाल औषधि अनुशन्धानशाला ,औषधिको वैज्ञानिक अनुसन्धान, परीक्षण र विश्लेषण गर्ने नेपाल सरकारको प्रमुख अंगको रुपमा रहेको छ। वि.सं. २०२१ सालमा वन तथा भू-संरक्षण मन्त्रालय, वन विभाग अन्तर्गत शाही औषधि अनुसन्धानशालाको नाममा औषधि सम्बन्धि मूल संस्थाको रूपमा स्थापित भई वि.सं. २०५० मा स्वास्थ्य तथा जनसंख्या मन्त्रालय अन्तर्गत ल्याईएको र औषधि ऐन, २०३५ को तेश्रो संशोधनबाट नाम परिवर्तन गरी शाही औषधि अनुसन्धानशाला भनि कायम भएको छ, जसलाई हाल राष्ट्रिय औषधि प्रयोगशालाको नामले चिनिन्छ। औषधिको गुणस्तर परीक्षण र नियमनको करिव ६० वर्षको इतिहास बोकेको एक मात्रै प्रयोगशाला हो।

राष्ट्रिय औषधि प्रयोगशालाले औषधि ऐन, २०३५ र त्यस अन्तर्गत बनेका नीति, नियमहरू, साथै राष्ट्रिय औषधि नीति, २०५१ र राष्ट्रिय स्वास्थ्य नीति, २०७६ अनुसार सुरक्षित, प्रभावकारी र गुणस्तरिय औषधिहरू आम जनतामा सहज उपलब्ध हुन औषधिहरूको परीक्षण, विश्लेषण र वैज्ञानिक अनुसन्धान गर्नु हो। औषधिहरू सुरक्षित, प्रभावकारी र गुणात्मक छन् भनी सुनिश्चित गर्न, प्रयोगशालाले योग्य र प्रशिक्षित विश्लेषकहरूबाट परीक्षण सेवाहरू प्रदान गर्दछ र यसको सेवाहरूमा पारदर्शिता, जवाफदेहिता, निष्पक्षता र एकरूपता प्रदान गर्ने लक्ष्य राख्छ ।साथै, यस प्रयोगशाला लाई अन्तरास्ट्रिय प्रमाणीकरण (ISO 17025:2017) गर्ने उदेश्य का साथ आगामी आ. व. ०८२/८३ मा प्रस्ताब गरिएको समेत जानकारी गराउछौ।

औषधिको परीक्षण र विश्लेषण, गुणस्तर नियन्त्रण तथा व्यवस्थापन, गुणस्तर तथा विधि पुष्टिकरण, माईक्रोबायोलोजिकल परीक्षण र विश्लेषण, खोपको प्रमाणीकरणसँग सम्बन्धित जानकारी गराउनका लागि पहिलो पटक प्रयोगशालाले वार्षिक बुलेटिन प्रकाशन गर्न लागेका छौ । यस बुलेटिनमा हामीले वर्षका प्रमुख उपलब्धिहरू, गुणस्तर नियन्त्रण प्रक्रिया, र प्रयोगशालाका विभिन्न शाखाहरूमा भएका सुधारहरू तथा चुनौती समावेश गरेका छौं। यस बुलेटिन भित्र समावेश गरिएका लेख रचनाहरु प्रयोगशालाका अधिकारिक भनाइ नभई सम्बन्धितको निजी विचारका रुपमा रहनेछ।

यस वार्षिक बुलेटिनलाई ज्ञान आदानप्रदान गर्ने, प्रयोगशालाको आवश्यकता र महत्त्व दर्शाउन, नीति निर्माणमा टेवा पुर्‍याउने माध्यमको रूपमा लिन सकिन्छ भन्ने कामना गर्दै बुलेटिन प्रकाशनमा यहाँहरुको बहुमुल्य सुझावको समेत अपेक्षा लिएको छौ।

अन्त्यमा यस वार्षिक बुलेटिन प्रकाशन गर्न आवश्यक सहयोग प्रदान गरिदिनु हुने प्रयोगशालाका श्रीमान निर्देशकज्युलाई मार्गदर्शन र सुझाबका लागि हार्दिक आभार ब्यक्त गर्दछौ।

Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory

VISION

An internationally recognized laboratory in the field of drug testing, research and analysis, as a principal body of the Government of Nepal to promote, promote and protect public health

MISSION

To achieve excellence in drug research, analysis, and testing

QUALITY POLICY

"National Medicines Laboratory is committed to perform tests of drug samples by delivering quality services with total commitment in compliance with current International Standards, National Regulatory Requirements and Good Laboratory Practice through involvement of competent workforce, by implementation of the policies, process, procedures and quality documentation and addressing risk and opportunities for continual improvement of the quality management system".

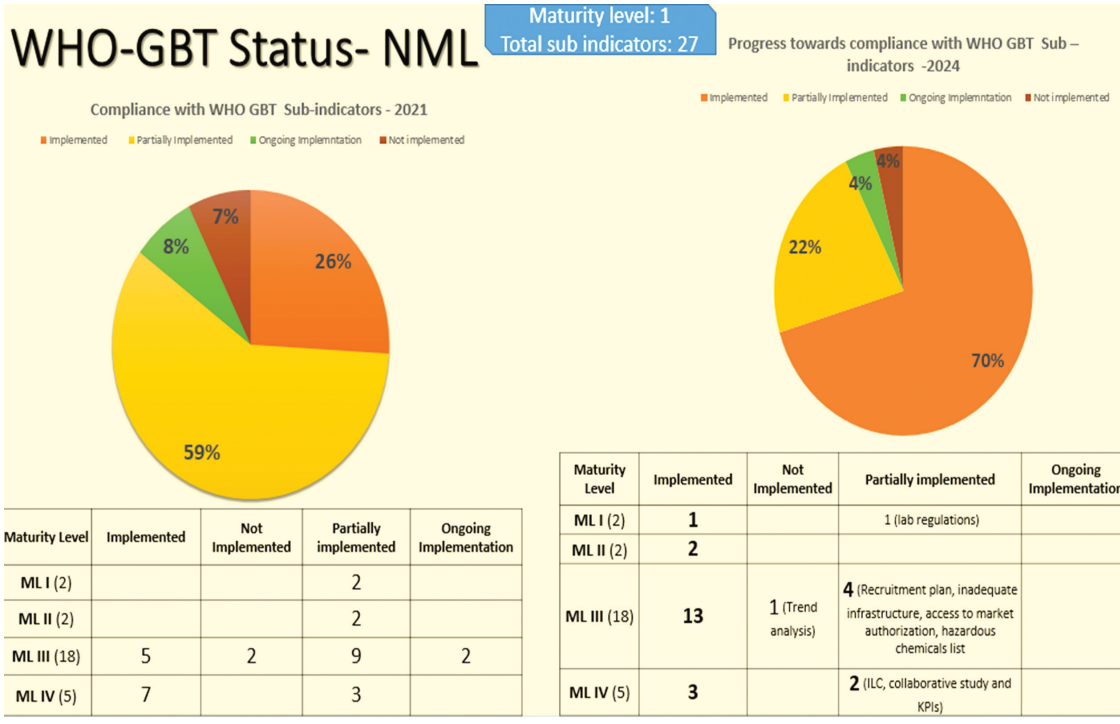
NML management and personnel work professionally, independently, and free from commercial, political, financial, and other pressures or alignments that can influence technical, quality and test results and fulfill ethics determined in accordance with the basic value and code ethics of government official of Nepal.

विषयसूची

Section -I
Overview of Institutional Activities

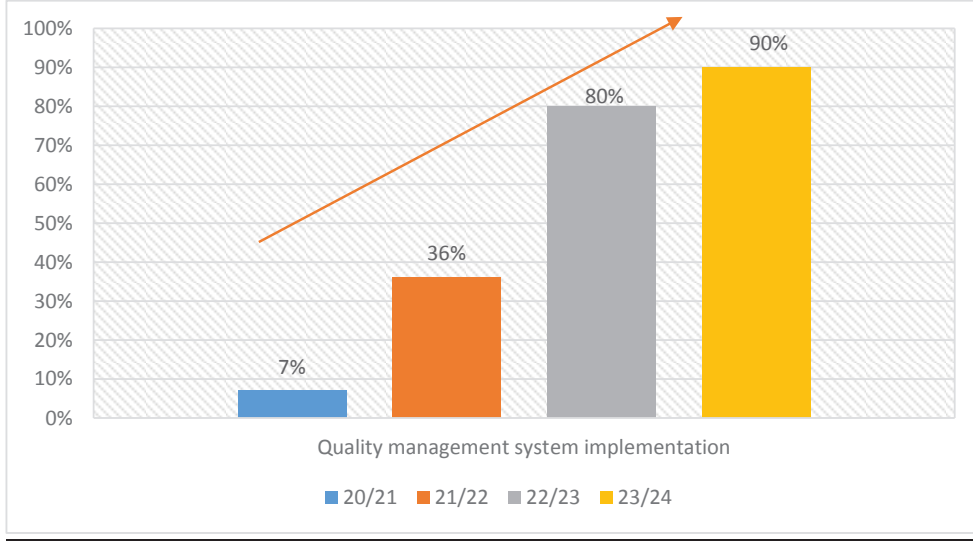
KEY OUTCOMES on Institutional activities and statistical report

1. WHO GBT indicator Laboratory Testing (LT) – Progress Summary



Maturity Level	Implemented	Not Implemented	Partially implemented	Ongoing Implementation
ML I (2)			2	
ML II (2)			2	
ML III (18)	5	2	9	2
ML IV (5)	7		3	

Maturity Level	Implemented	Not Implemented	Partially implemented	Ongoing Implementation
ML I (2)	1		1 (lab regulations)	
ML II (2)	2			
ML III (18)	13	1 (Trend analysis)	4 (Recruitment plan, inadequate infrastructure, access to market authorization, hazardous chemicals list	
ML IV (5)	3		2 (ILC, collaborative study and KPIs)	



2. Overview of WHO GBT

विश्व स्वास्थ्य संगठनद्वारा स्थापित वैश्विक मापदण्ड विधि (WHO GBT) बमोजिमको विश्लेषण अनुसार हाल प्रयोगशाला को क्षमता न्यूनस्तर (maturity level 1) मा रहेको अवस्था छ।

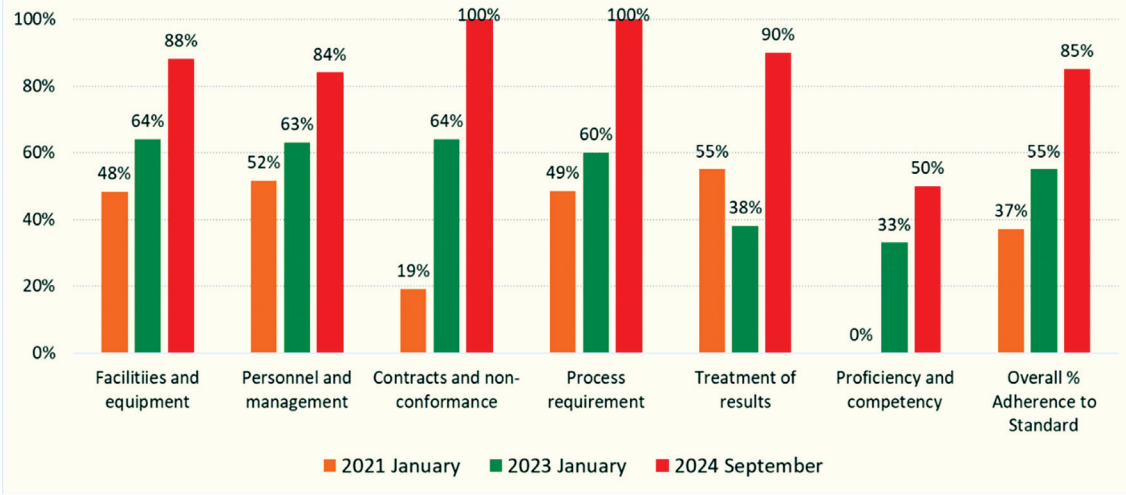
Total: 22/22 Indicators (Maturity level 1 status)		
Status	**2021**	**2024**
Not Implemented/NA*	5	1
Ongoing Implementation	1	1
Partially Implemented	16	6
Implemented	0	14

Laboratory Testing (LT)

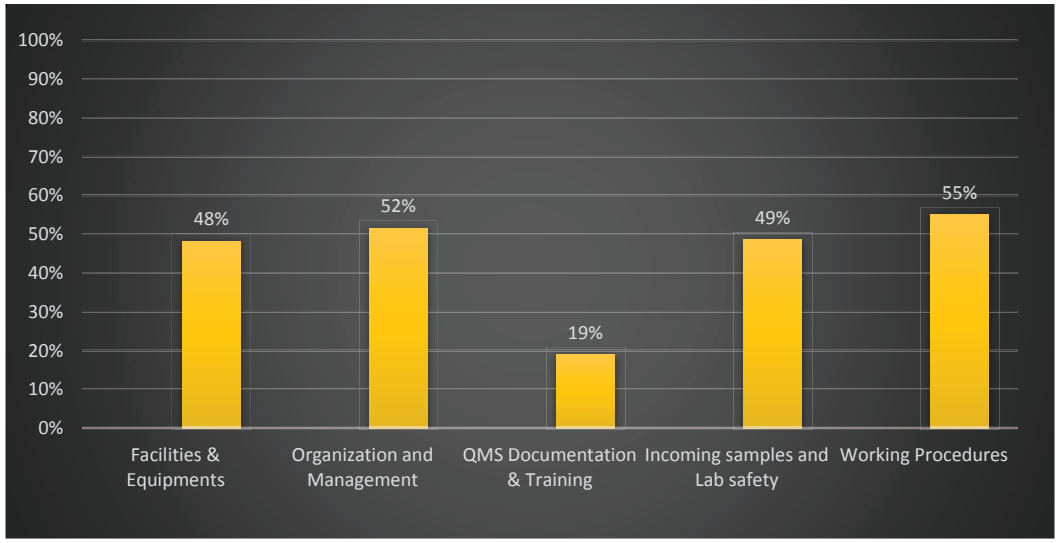
Documents/Activities	**Status**	**Indicator Relevance**
Quality Manual	Approved	LT02.01
SOPs	Approved	RS05, LT03
Warehouse management with installation of racks	Completed	RS08.01
Quality Management Unit	Established	RS05.02
Five-year strategy	Finalized by Steering Committee	RS03.02
Hands-on training	Implemented and ongoing	LT04

ISO 17025: 2017 compliance over the years

Stepwise assessment tool towards accreditation (SATTA) progress report

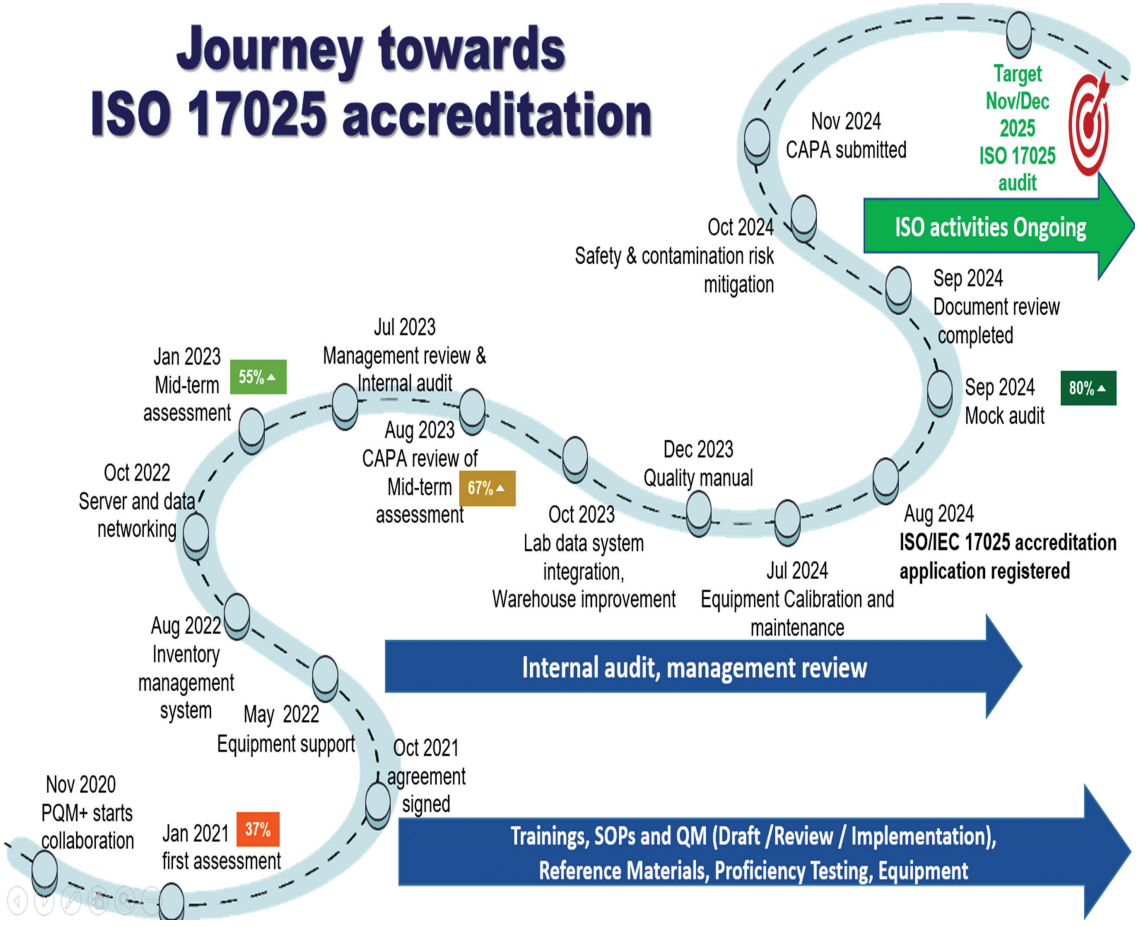


NML status



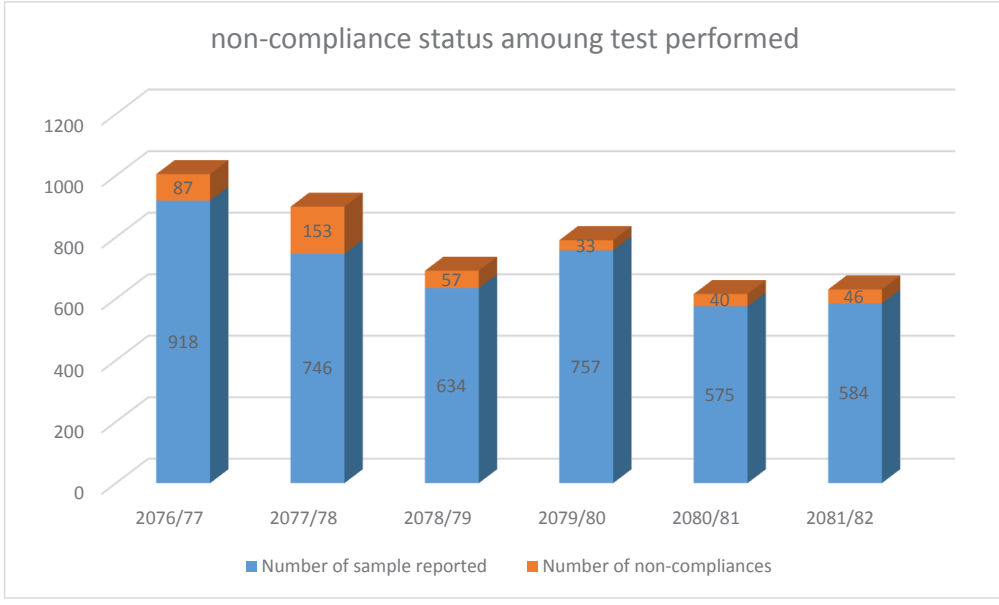
(overall score 67% in 2024)

Proposed roadmap of NML towards ISO17025 accreditation supported by USAID PQM plus support

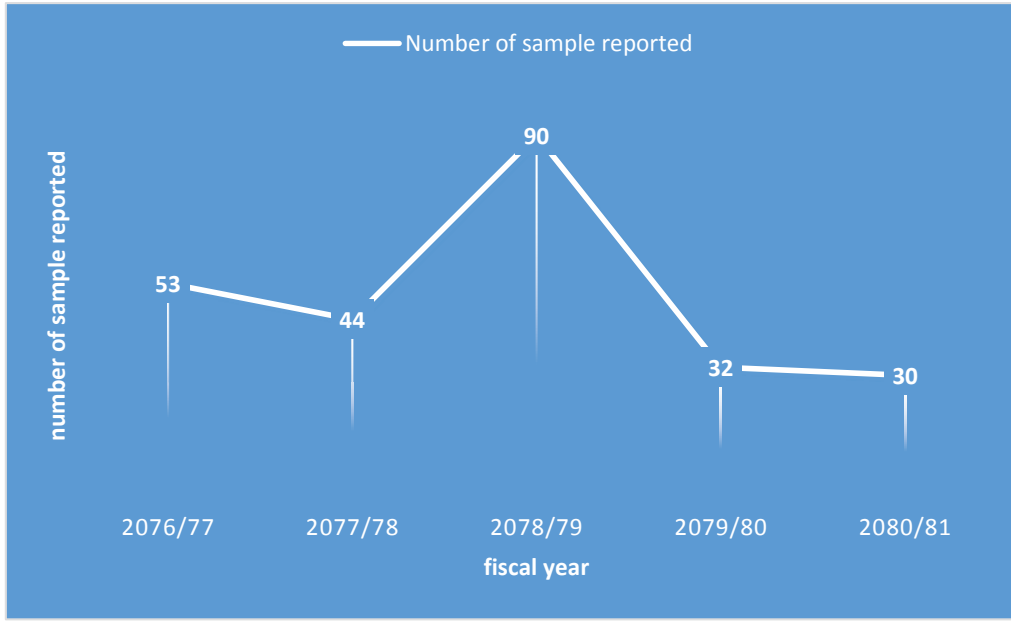


Trend analysis of NML data

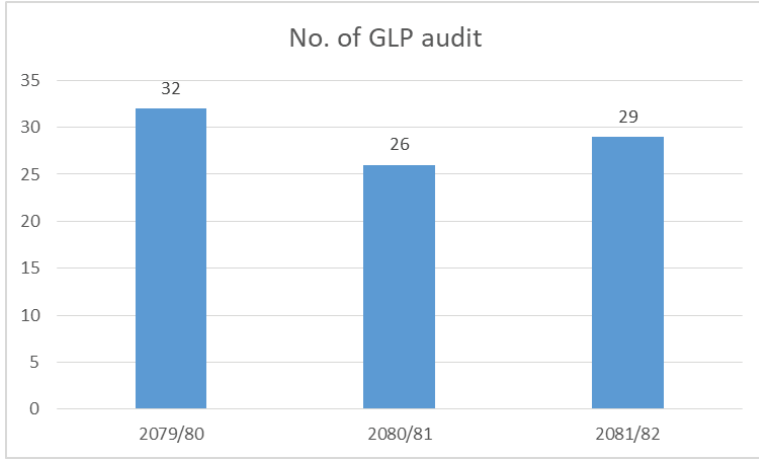
1. Trend analysis of number of sample reported and non compliance for last six years of NML



2. Trend analysis of number of vaccines lot release done for last five years of NML

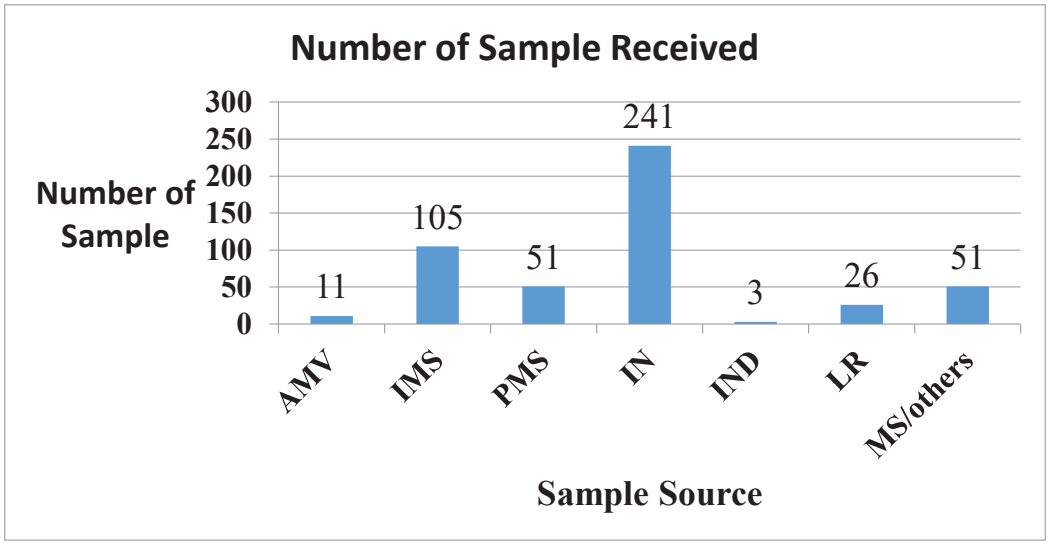


3. Trend analysis of number of GLP audit conducted for last three years of NML



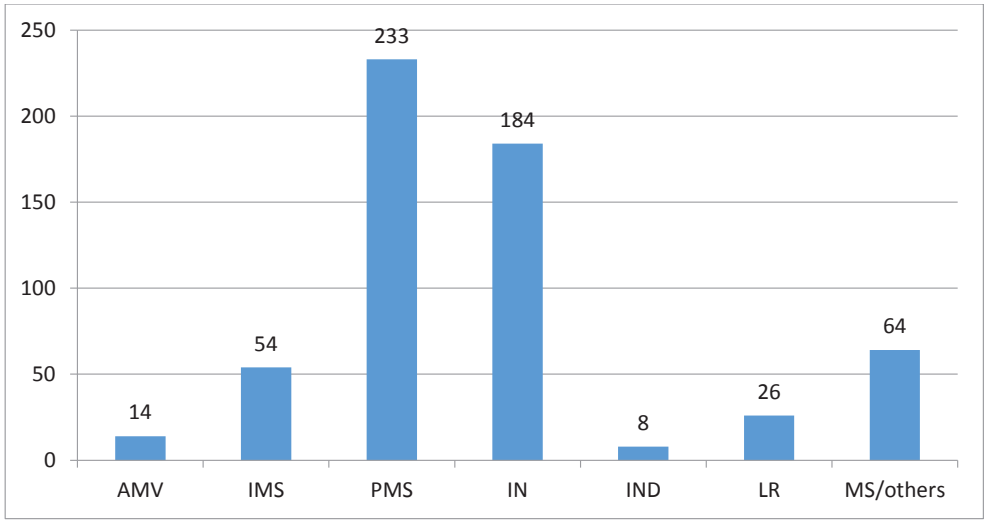
आर्थिक बर्ष २०८१/२०८२ को बार्षिक प्रगति विवरण

नमूना प्राप्त संक्षेप २०८१/८२

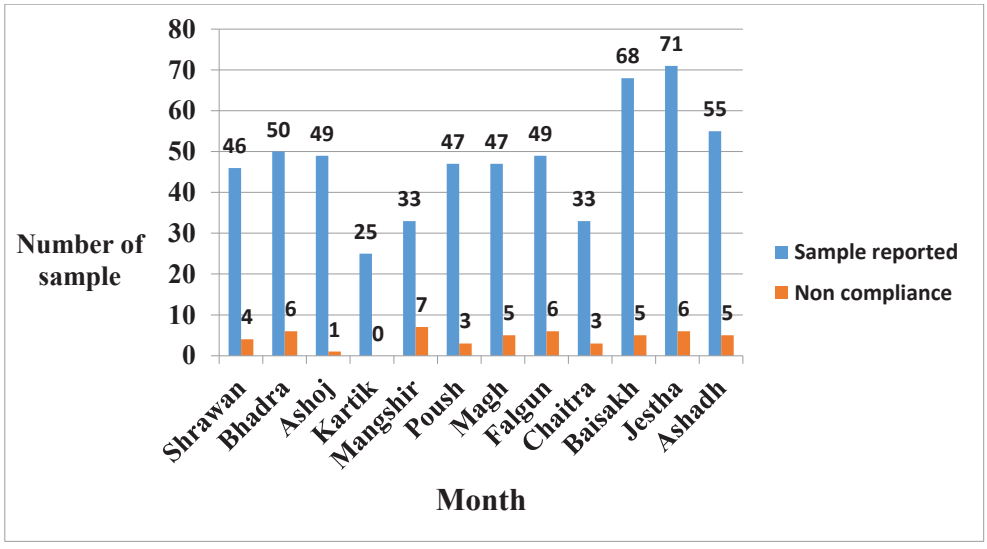


Total number of sample received in fiscal year: 488

नमूना प्रतिबेदन संक्षेप २०८१/८२ (as of 20/03/2082)



न्यून गुणस्तर भएका नमुनाको संक्षेप (as of 20/03/2082)



Total number of sample tested: 584

Noncompliance: 8.69%

आ. व. ८१/८२ को विनियोजित बजेट

पुजीगत : ३,५७,५०,०००/-

चालु : ४,९७,१७,०००/-

कुल बजेट : ८,५४,६७,०००/-

आ.व. ८१/८२ मा परीक्षण र विश्लेषण गर्दा गुणस्तर नभएका औषधीहरू (with Non-Compliance Parameter)

S.N.	Sample name	Manufacturer	Batch No.	Mfg Date	Exp Date	Non-Compliance parameter
1	Lobenz- 1 tab Lorazepam 1 Mg	Grace pharmaceuticals Pvt.ltd.	TLOF-001	NOV.2023	OCT. 2025	Assay
2	Obest, Ofloxacin Oral Suspension IP	Apex pharmaceuticals	L-80023	Jun-23	May-25	Fill Volume
3	Oflacin, Ofloxacin Oral Suspension IP	Amtech med. pvt.ltd	OFL 222	Jun-23	May-25	Fill Volume
4	Ol, Ofloxacin Oral Suspension IP	Leben laboratories pvt. ltd,india	L 823	Jun-23	May-25	Fill Volume
5	Azol Suspension	Curex Pharmaceuticals Pvt. Ltd	LAZ-048	Dec-22	Nov-24	Assay
6	Evacip E/E Drops, 5 ml	Everest Parenterals Pvt. Ltd	ECE 221	Feb-24	Jan-26	Sterility
7	Biotax 250 mg, Injection	Zydus Healthcare Ltd. India	F300466	May-23	Apr-25	Description
8	Montriz Syrup	Lomus Pharmaceuticals Pvt. Ltd.	MZS-0124	Jan-24	Dec-25	Physical (Leakage)
9	Azol Suspension	Sceptre medical(1) Pvt. Ltd India	SPA/24/026	Jun-24	May-26	Assay
10	Baccirub 5 litre	Raman and Weil Pvt.Ltd, India	BC1-24115	Jul.2024	Jun.2026	Assay
11	Baccirub 500 ml	Raman and Weil Pvt.Ltd, India	BC1-24113	Jul.2024	Jun.2026	Assay
12	Baccirub 100 ml	Raman and Weil Pvt.Ltd, India	BC1-24114	Jul.2024	Jun.2026	Assay
13	Kaftus-D Syrup	Sumy Pharmaceuticals pvt. Ltd,Nepal	KFD-37	Jan.2024	Dec.2025	Leakage
14	Panoflam Suspension	Simca Laboratories Pvt. Ltd, Nepal	L-22/168	Dec.2022	Nov.2025	Leakage

S.N.	Sample name	Manufacturer	Batch No.	Mfg Date	Exp Date	Non-Compliance parameter
15	Airosal Syrup	Nova Genetica Pvt. Ltd,Nepal	LSS-98	Mar.2024	Feb.2026	Leakage
16	CODEP Tablets	Lomus Pharmaceuticals Pvt.Ltd, Nepal	CD-0122	Jan.2022	Dec.2024	Assay
17	Itral	Curex Pharmaceuticals Pvt. Ltd, Nepal	CCT-033	Mar.2023	Feb.2025	Label claim
18	Calcigen-F	Nova Genetica Pvt. Ltd,Nepal	CVD3-267	June.2023	May.2025	Assay
19	Calcigen-F	Nova Genetica Pvt. Ltd,Nepal	CVD3-264	Mar.2023	Feb.2025	Assay
20	Calbone	Curex Pharmaceuticals Pvt. Ltd	TCL-229	Aug-23	Jul-25	Identification
21	Evacip E/E Drops	Everest Parenterals Pv Ltd	ECE 140	Jan-23	May-25	Sterility Test
22	DNS	Lomus Parenterals Pv Ltd	A04W2010	Jan-25	Dec-25	Sterility Test
23	Linics M 1000	Pharmonics Lifesciences Pvt Ltd	29010	Mar-25	Feb-25	Assay
24	Incret-m 1000	Magnus Pharma Pvt. Ltd	KM23001	Apr-25	Mar-25	Assay
25	Fetine-180	Curex Pharmaceuticals Pvt. Ltd	TFN2-012	Sep-23	Feb-25	Assay
26	Superzole-100	Supreme Healthcare Pvt. Ltd	SUC.23006	Nov.23	Oct.25	Assay
27	GHC Disinfectant spray	Global Healthcare	108-24	Aug-24	Jul-27	Assay
28	Mi-Shield Rub	Zenith Micro Control	ZFA001/05/24	Sep-24	Aug-27	Assay
29	Pandom 40	Supreme Healthcare Pvt. Ltd	PAT.23038	Apr-23	Mar-25	Dissolution
30	Airtel-40	Royal Pharmaceuticals Pvt. Ltd, Nepal	40-7	Apr. 2023	March.2025	Dissolution
31	PILPAN	Psychotropics India Limited	CI643008	Oct.2023	Sep.2025	Sterility test
32	Acitop 40 mg	Aristo Pharmaceuticals Pvt.Ltd	MPJ233487	Sep.2023	Aug.2025	Sterility test
33	Airtel-20	Royal Pharmaceuticals Pvt. Ltd, Nepal	72-4	Jun. 2023	May.2025	Dissolution

S.N.	Sample name	Manufacturer	Batch No.	Mfg Date	Exp Date	Non-Compliance parameter
34	Rectified spirit B.P	Lifeline Drop Pvt.Ltd, Nepal	LLDPL-APRS021	Mar.2024	Feb.2027	Assay
35	DOPAN-DSR	Siddhartha Pharmaceuticals Pvt. Ltd	DPSC-3301	Aug.2023	July.2025	Assay
36	Pandom-DSR	Supreme Healthcare Pvt. Ltd	PAC.24052	Apr. 2024	Mar.2026	Assay
37	Pantafast- DSR	Arya Pharmalab Pvt. ltd	PFDC.01041	Apr. 2024	Mar.2026	Assay
38	Aglocef 1 G	Aglowmed Ltd, Mumbai	N192403	May.2024	Oct.2026	Sterility test
39	Calcifer Drops	National Healthcare Pvt. Ltd,Nepal	CLLF23014	Nov.2023	Nov.2025	Assay
40	Calcifer Drops	National Healthcare Pvt. Ltd,Nepal	CLLF23012	Oct.2023	Oct.2025	Assay
41	RL 500 ml	Lomus Parenterals Pvt. Ltd.	A0581030	Oct. 2024	Sep.2026	Sterility test
42	D5% 500 ml	Lomus Parenterals Pvt. Ltd.	A0181004	Nov.2024	Oct.2026	Sterility test
43	Povine	Curex Pharmaceuticals Pvt.Ltd.	LPS5-023	May.2024	Apr. 2026	Assay
44	Calcifer Drops	National Healthcare Pvt. ltd.	CLLF23014	Nov.2023	Nov.2025	Assay
45	Zinko fast DT	Royal Pharmaceuticals Pvt.ltd.	76-10	Apr.2024	Mar.2026	Disintegration Test
46	Cetophen	Lomus Pharmaceuticals Pvt.ltd.	CTT-1624	Aug.2024	Jul.2027	Dissolution
47	Merocef 200 DT	Royal sasa Nepal Pharmaceuticals Pvt.ltd.	MET050	Aug.2024	Jul.2026	Disintegration Test
48	Pantoloc	Curex Pharmaceuticals Pvt.Ltd	TPT-129(B)	Dec.2024	Nov.2027	Dissolution

आ. व. ८१/८२ को Good laboratory practice audit list

S.No.	Name of the Pharmaceutical Industry/ Laboratory	Address
1	Nepal Research Laboratory (NRF)	Birgunj
2	Everest Parenterals Pvt. Ltd.	Birgunj
3	National Healthcare Pvt. Ltd.	Birgunj
4	Bhaskar herbaceuticals	Birgunj
5	Quest Pharmaceuticals	Birgunj
6	Apex Pharmaceuticals	Birgunj
7	Nepal Pharmaceutical Laboratory (NPL)	Birgunj
8	Pharmonics Life Sciences Pvt. Ltd,	Biratnagar
9	Amtech Med Pvt. Ltd	Biratnagar
10	Nippon Pharmaceuticals Pvt. Ltd	Biratnagar
11	Shiv Pharmaceutical Laboratories	Biratnagar (Dharan)
12	Accord Pharmaceuticals Ltd	Mahalaxmi-8, Lubhu, Lalitpur
13	Lomus Pharmaceuticals Pvt. Ltd.	Kageshwori Manohara, Kathmandu
14	Nepal Aushadhi Ltd	Babarmahal, Kathmandu
15	Kasturi Pharmaceuticals (P.) Ltd	Chitwan
16	Om Megashree Pharmaceuticals Ltd	Chitwan
17	Royal Sasa Nepal Pharmaceuticals Pvt. Ltd.	Chitwan
18	Royal Pharmaceuticals Pvt. Ltd.	Chitwan
19	Everest Pharmaceuticals Pvt. Ltd	Bhaktapur, Nepal
20	Sopan Pharmaceuticals Ltd	Mahalaxmi Municipality- 8, Lalitpur, Nepal
21	Deurali-Janta Pharmaceuticals Pvt. Ltd,	Dhapasi, Kathmandu, Nepal
22	Lomus Parenterals and Formulations Pvt. Ltd,	Dhanusa, Nepal
23	Supreme Healthcare Pvt. Ltd	Bara, Nepal
24	M.D.H. Pharmaceuticals Pvt. Ltd.	Bhaktapur, Nepal
25	Ohm Pharmaceuticals Laboratories Pvt. Ltd.	Bhaktapur, Nepal
26	Tizig Pharma Pvt. Ltd.	Banepa, Nepal
27	Multi Pharmaceutical Laboratories Pvt. Ltd.	Kupondole, Lalitpur
28	Zest Laboratories and Research Center Pvt. Ltd,	Bhaktapur, Nepal
29	Global Reference Laboratories Pvt. Ltd.	New Baneshwor

Section II
Articles

राष्ट्रिय औषधि प्रयोगशाला : सिंहावलोकन

सचिता जोशी, बरिष्ठ गुणस्तर नियन्त्रक

औषधि ऐन, २०३५ द्वारा स्थापित नेपाल सरकारको एक मात्र औषधि परीक्षण तथा विश्लेषण गर्ने "राष्ट्रिय औषधि प्रयोगशाला" ले स्वदेशमा उत्पादित तथा बजारीकृत औषधिहरूको गुणस्तर यकिन गर्न औषधिको गुणस्तर परीक्षण र नियमन गर्दै आएको छ। समय को माग अनुसार प्रयोगशाला ले विभिन्न औषधिहरूको गुणस्तर यकिन गर्न अन्तर्राष्ट्रिय मान्यता एवम् मापदण्ड बमोजिमको गुणस्तर परीक्षण गर्नु पर्ने हुदा धेरै चुनौती हरु देखिएका छन्। बजारमा उपलब्ध सबै औषधि मात्र नभई प्रविधिजन्य स्वास्थ्य सामग्री समेतको गुणस्तर परीक्षण गर्नु पर्ने हुदा एस प्रयोगशाला को जिम्मेबारी महत्वोपूर्ण रहेको छ ।प्रयोगशाला संचालनका लागि आफ्नै भवन रहेता पनि आगामी दिनहरुमा औषधिको परीक्षण तथा विश्लेषण बाहेक स्वास्थ्यजन्य सामग्री तथा cosmetics, औषधिमा भेटेरिनेरी, आयुर्वेद र वैकल्पिक चिकित्सा प्रणाली, biologicals/biosimilars तथा vaccines/sera, को गुणस्तर एकिन गर्न परीक्षण तथा विश्लेषण गर्नुपर्ने हुदाँ नया भवनको आवश्यकता देखिन्छ ।अहिलेको भवनमा पनि खोप तथा biological, cytotoxic drugs को परीक्षण गर्न BSL level 2 को infrastructure आवश्यकता भएको हुदाँ नयाँ भवनको प्रस्ताव अति आवश्यक रहेको छ। साथै प्रयोगशालालाई आगामी दिन मा ISO: 17025 accreditation तथा WHO prequalification प्रमाणित प्रयोगशाला बनाउन नयाँ तरिकाको प्रयोगशालाको कल्पना गर्नुपर्ने देखिन्छ।

राष्ट्रिय औषधि प्रयोगशालाको औचित्य, संचालन र विकासको लागि राष्ट्रिय औषधि नीति सन् १९९५, राष्ट्रिय स्वास्थ्य नीति, २०७६, सोह्रौँ योजना (२०८१/८२-२०८५/८६), नेपाल स्वास्थ्य क्षेत्र रणनैतिक योजना (NHSSP) २०२३-२०३०, राष्ट्रिय स्वास्थ्य वित्त नीति २०८०-२०९० मा नीतिगत तथा कानूनी व्यवस्था गरेको पाइन्छ ।तसर्थ, औषधि ऐन, २०३५ को व्यवस्था बमोजिम औषधिको वैज्ञानिक अनुसन्धान, परीक्षण र विश्लेषण सम्बन्धी नियमावली तयार गरी औषधिको उच्चतम तहको गुणस्तर, सुरक्षा र प्रभावकारीता कायम गर्नका लागि आवश्यक नियम, कार्यविधि र मापदण्डको तर्जुमा गर्नुपर्ने देखिन्छ । प्रयोगशालाबाट प्रदान गरिने सेवालाई ISO:17025 accreditation को आवश्यकता अनुसार पारदर्शी, जवाफदेही र व्यावसायिक बनाउन र सन्दर्भ प्रयोगशालाको रूपमा विकास गर्न रणनैतिक उद्देश्य र लक्ष्य आवश्यक देखिन्छ।

प्रयोगशालाको वि.स. २०७५ सालमा स्वीकृत Organogram अनुसार ४० जनाको दरबन्दी रहेको अवस्थामा देश तथा विदेशको औषधिको गुणस्तर यकिन गर्न मुस्किल रहेको हुदाँ र साथै परीक्षण तथा विश्लेषण दायरा बढाउनु पर्ने जस्तै स्वस्थजन्य सामग्री तथा सौन्दर्य प्रशोधन आदिको नियम गर्न शाखाहरु थप गरी साथै थप बहु-अनुशासनात्मक जनशक्ति छिटो भन्दा छिटो थप गरी परिमार्जन गर्नु पर्ने नितान्त जरुरी देखिन्छ । तसर्थ, प्रयोगशालाको रणनैतिक कार्ययोजनामा औषधि परीक्षण सेवाको बढ्दो क्षेत्र र मागलाई मध्यनजर गरी नयाँ भवन

र संगठन तथा व्यवस्थापन सर्वेक्षण (O&M) गर्न पहिलो प्राथमिकता रहेको छ । सबै शाखा, ईकाई र जनशक्तिको स्पष्ट कार्यविवरण पुनरावलोकन गरी लागु गर्नु पर्ने देखिन्छ। उपयुक्त सीप समिश्रण सहितको व्यावसायिक, क्षमतावान, दक्ष जनशक्ति विकास गर्नुपर्ने छ । आधुनिक विकासको तिव्रतामा पेशागत क्षमता विकासको लागि निरन्तर र नियमित औषधि अध्ययन प्रणालीको विकास गर्न संलग्न जनशक्तिको लागि नियमित क्षमता र दक्षता विकासका कार्यक्रम संचालन गर्ने साथै अन्तर्राष्ट्रिय स्तरमा संचालन हुने तालिममा सहभागी गराई गुणस्तर सेवा प्रदान गर्नुपर्ने देखिन्छ । प्रयोगशालाको रणनीतिक लक्ष्यमा ISO 17025:2017 प्रमाणीकरण प्राप्त गरी गुणस्तरीयता र प्रभावकारी, विश्वसनीयता वृद्धि गर्ने र भविष्यमा थप WHO Prequalification कार्यक्रमले तय गरेका मापदण्ड पूरा गरी WHO Prequalification प्रमाणपत्र प्राप्त गरी अन्तर्राष्ट्रिय मान्यता हासिल गर्ने रहेको छ। यस प्रयोगशालालाई केन्द्रीय प्रयोगशाला को रुप मा स्थापना गरी संघीयताको मर्म अनुरूप प्रदेश तहमा औषधि परीक्षण प्रयोगशाला स्थापनाको प्रारम्भ गर्नुपर्ने देखिन्छ।

हाल प्रयोगशालामा परीक्षण तथा विश्लेषण गर्न आधुनिक उपकरण, जस्तै High-Performance Liquid Chromatography - HPLC, Gas Chromatography- GC, AAS, FTIR, LC-MS-MS, biosafety cabinet लगायत अन्य उपकरणहरूको उपलब्धता रहेको छ। आगामी दिनमा स्वस्थ्यजन्य सामग्री परीक्षण तथा विश्लेषण गर्नुपर्ने अवस्थामा physical testing, chemical testing र biological testing का लागि थप उपकरण आवश्यक हुन्छ ।स्वस्थजन्य सामग्रीको biological test गर्न BSL-2 lab आवश्यक हुने हुदाँ यसको लागि प्रयोगशालाको दिगो आर्थिक श्रोतको सुनिश्चितता गर्नुपर्ने देखिन्छ। साथै औषधि परीक्षण सम्बन्धी मै पनि anticancer drugs testing, hormone testing साथै आवश्यक परेमा खोपको परीक्षण तथा विश्लेषणको लागि चाहिने भौतिक संरचना र उपकरण व्यवस्थापन गर्न पनि बजेटको सुनिश्चितता गर्नु पर्ने देखिन्छ ।प्रयोगशालामा संचार प्रविधि सूचना व्यवस्थापन प्रणाली (Electronic Laboratory Information Management System-ELIMS) व्यवस्थित गर्नु अति आवश्यक भएको हुनाले यसमा बजेट व्यवस्थापन हुनु पर्नेछ।

औषधिको विश्लेषण, परीक्षण र अनुसन्धान गर्ने विभिन्न सरकारी तथा गैरसरकारी संघसंस्था र निजी प्रयोगशालाहरूसँग समन्वय र सहकार्य, राष्ट्रिय तथा अन्तर्राष्ट्रिय संघसंस्थाहरूसँग समझदारी गरी एस प्रयोगशाला को औषधि परीक्षण तथा विश्लेषण मा थप क्षमता विस्तार गर्नु आज को आवश्यकता हो। अन्त्यमा, यस राष्ट्रिय औषधि प्रयोगशाला नेपाल सरकारको एक मात्रै औषधि परीक्षण तथा विश्लेषण गर्ने प्रयोगशाला भएको ले एसको विकास गर्न र उद्देश्य हासिल गर्न सम्बन्धित सबै निकाएहरुको ध्यानाकर्षण हुनुपर्ने र यसलाई प्राथमिकतामा राख्नु पर्ने अत्यन्त जरूरी देखिन्छ।

Nepal's Pharmaceutical Quality Control Laboratory: Deficiencies and Current Trends

Saraswati Dangol- Senior Quality Controller

The quality control department of the pharmaceutical industry plays a vital role in ensuring the safety, efficacy, and quality of pharmaceutical products. These laboratories conduct rigorous testing and analysis to verify that products comply with regulatory standards. As the results of the drug substances are directly linked to human health, pharmaceutical quality control laboratories must adhere to the requirements approved by the National Regulatory Authority (NRA), Department of Drug Administration (DDA).

The DDA conducts Good Manufacturing Practice (GMP) audits in accordance with WHO GMP guidelines and the National GMP code, while the National Medicines Laboratory (NML) carries out Good Laboratory Practice (GLP) audits as part of its annually approved program. The audit criteria for good practices in laboratories include Annex 1 — WHO Good Practices for Pharmaceutical Quality Control Laboratories (WHO TRS No. 957, 2010), Annex 2 — WHO Good Practices for Pharmaceutical Microbiology Laboratories (WHO TRS No. 961, 2011), and the International Standard ISO/IEC 17025:2017, which outlines the general requirements for the competence of testing and calibration laboratories.

Some quality control laboratories in Nepal exhibit notable deficiencies in both their quality management systems and infrastructure. These issues include inadequacies such as the absence of essential components in their Quality Manual (as per WHO GMP guidelines) and insufficient implementation of quality system procedures (including control of documentation, control of records, internal audits, handling of complaints, CAPA procedures, change control, management of deviations, disposal of reagents and samples, management of out-of-specification results, safety procedures, and quality risk management).

In addition to addressing these deficiencies, pharmaceutical quality control laboratories should focus on monitoring the expiry dates of reagents and working standards, maintaining an approved list of reagent suppliers, verifying the quality of various grades of water used

for testing, and segregating controlled, toxic, flammable, volatile reagents, and self-igniting materials (such as metallic sodium and potassium). They should also ensure up-to-date status of the calibration of equipment. Proper implementation of procedures for handling reference standards must be ensured to maintain their quality. Some laboratories are unaware of the requirement to verify the current lot of pharmacopoeial primary reference standards.

Manual data handling is still predominant, increasing the risk of errors. This highlight the necessity of Laboratory Information Management Systems (LIMS) to ensure traceability and data integrity. Data integrity issues observed in some laboratories include common password sharing, users being given software privileges to modify methods and integrations, inadequate computer system controls, and audit trail functionality being turned off within systems. It is important to note that not all the deficiencies mentioned above apply to every pharmaceutical company. Some laboratories are much more updated and adhere closely to good laboratory practice guidelines. Nevertheless, there is a positive trend toward addressing these deficiencies through increased awareness of medicine quality, investment in infrastructure, regulatory reforms, and a stronger focus on quality management systems.

The pharmaceutical industry should prioritize investing in laboratory infrastructure according to NRA guidelines, developing skilled human resources, and procuring advanced equipment essential for accurate and reliable testing. Continuous professional development and training programs should be implemented to improve the competency of laboratory personnel. Procedures for good documentation practices and control of records should be established to ensure the traceability and accountability of test results. Additionally, the proper implementation of approved procedures should be regularly monitored. Enhancing regulatory compliance and adopting comprehensive quality management systems will further strengthen the capabilities of QC laboratories, ensuring the safety, efficacy, and quality of pharmaceutical products.

References

1. World Health Organization (WHO). (2010). *WHO Good Practices for Pharmaceutical Quality Control Laboratories* (Annex 1, WHO Technical Report Series No. 957).
2. World Health Organization (WHO). (2011). *WHO Good Practices for Pharmaceutical Microbiology Laboratories* (Annex 2, WHO Technical Report Series No. 961).
3. International Organization for Standardization (ISO). (2017). *ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories*.
4. Good Laboratory Practice audit report of National Medicines Laboratory

Method Validations: A Focus on Challenges

Laxman Bhandari -Senior Divisional Chemist (NML)

1. Introduction:

Quality means fitness for use. Safety, potency, efficacy, stability, acceptability and regulatory compliance criteria must be fulfilled to produce a quality pharmaceutical product. Method validation is a critical, challenging and time-consuming activity in the pharmaceutical analysis. In today's globalized world, method must give the correct, sufficiently accurate, precise, reliable, comparable measurement results along with robustness of the method. The development of a validation method study is not just fulfilling the checklist exercise but the true purpose of an analytical method validation is to establish the acceptable operating range of a method and ensure highest possible quality product and assurance. The focus shouldn't be simply be on meeting the standard and arbitrarily selected criteria. Acceptance criteria must be appropriate as they directly affect the quality of the data that it will generate. Before undertaking the task of methods validation, it is necessary that the analytical system itself should be adequately designed. Suitability of the instruments, suitability of reference standard and materials, suitability of analysis, suitability of documentation as well as status of training and qualification records shall be well maintained. Planning a series of performance characteristics of analytical method validations for a regulatory filing requires careful forethought. A well- designed method validation study should provide valid data, authorized references, sensitivity of the test data within a specific range and reliable statistical analysis.

2. Method Validation

According to United State Pharmacopeia (USP); method validation is the process which meets the requirements for the intended analytical application whereas International Conference on Harmonization (ICH) defined it as appropriate for an intended use that is fit for purpose. According to current ICH Q2(R1) guidelines there are certain key performance characteristics listed for method validation namely specificity, accuracy, recovery, precision, repeatability, intermediate precision,

linearity, range, limit of detection (LOD), limit of quantitation (LOQ), robustness and ruggedness. Moreover, system suitability is fundamental.

The main purpose of the method validation is to minimize analytical and instrumental error, to give reliable, accurate and reproducible results in accordance with the given specification of the test method. To ensure the quality of test results, to meet accreditation requirement, objective evidence for defense against challenges, to be assured of the correctness of results, and ensure comparability with measurements made in other laboratories method validation is required.

According to ISO/IEC 17025:2017, the laboratory must select appropriate latest valid version of method, verified it prior to use for required performance and validation the non-standard of methods. When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

The fundamental guidelines for analytical method validation are:

Guidelines	Details
ICH guidelines	ICH Q2 (R1): Validation of Analytical Procedures: Text and Methodology Q2 (R1)
ISO/IEC 17025:2017	Clause 7.2 selection, verification and validation of methods
USFDA guidance	for industries on analytical method validation
WHO	method validation guidelines
USP pharmacopeia general chapter	**explain about below**
USP <1225>	validation of analytical procedures
USP <1226>	verification of compendia procedures
USP <1224>	transfer of analytical procedures,
USP <1210>	explain about statistical tool for procedure validation
USP <1010>	is about analytical data: interpretation and Treatment,
USP <621>	for chromatography, can be adjusted or changed without the need for revalidation.
USP <1092>	is for the dissolution procedure validation.

Guidelines or standard operating procedure (SOP), validation protocol, acceptance criteria, validation report and summary of conclusion of validation with declaration are prerequisites documents for method validation. All personnel who will perform the validation testing must be properly trained. For each of the validation characteristics in the document should defines the test procedure, documentation, and acceptance criteria. Prior to introducing a new, unknown method, every conscientious analyst

will first carry out its validation. This is done out of professional conscience and aspiration to provide reliable measurement results, i.e. results on which the right decisions can be made.

3. Performance characteristics in method validation:

Type	Identification	Impurities		Assay
Characteristics		Quant.	Limit	- Dissolution, - Content
Accuracy	-	+	-	+
Precision	-	+	-	+
Repeatability	-	+	-	+
Interm. precision	-	+(1)	-	+ (1)
Specificity (2)	+	+	+	+
Detection Limit	-	- (3)	+	-
Quantitation Limit	-	+	-	-
Linearity	-	+	-	+
Range	-	+	-	+

(1) In cases where reproducibility has been performed, intermediate precision is not needed

(2) Lack of specificity of one analytical procedure could be compensated by other supporting analytical procedure(s)

(3) May be needed in some cases

4. Documentation

I. Validation Protocol This document will have the following elements:

1. Purpose of validation
2. A description of the main principle of the test procedure/method
3. A description of the test procedures and the test conditions
4. Details of the equipment/facilities to be used, together with its calibration status
5. The variables to be monitored
6. The samples to be taken - where, when, how, and how many
7. Performance characteristics/ attributes to be mentioned, together with the best methods
8. The acceptance limits, Time schedules, Personnel responsibilities
9. Details of methods for recording and evaluating results, including statistical analysis.
10. Raw data, formula and calculation and chromatograms and associated documents
11. References of the procedures

II. Validation Report This document will have the following elements:

1. Purpose of the validation
2. A description of the test methods
3. Test data from validation batches
4. Evaluation, comparison with the reference substances, and recommendations
5. Formal acceptance/rejection of the work by the team/persons designated

6. Report as per the protocol mention.
7. Signature and authorization

5. Common Issues and challenges while reviewing the document in method validations:

Method validation can be challenging due to several factors, including the complexity of modern analytical techniques, the need to address inherent variability in materials and processes, and the evolving nature of regulatory requirements. Some of the challenges during method validation are:

1. Due to their complex molecular characteristics, manufacturing processes, and inherent variability in starting materials method validation and require specialized approaches.
2. Method validation is constantly evolving, meeting regulatory standards, including documentation and quality control, can be costly and time-consuming.
3. The performance of chromatography columns can vary between batches and with age, requiring careful consideration during method development and validation and sample preparation or sample handling can introduce errors and affect method performance. Identifying and addressing potential interferences in the sample matrix can be crucial for accurate results. The problems of column failure or injector malfunction before they occur; as well as investigating anomalous incidents that occur during routine testing. Column temperature fluctuated and required additional optimization. It requires and allows smooth transfer of the validated method between the testing laboratories. Not all the validation processes end well.
4. Insufficient human resources, efficiency issues, and inadequate technological infrastructure can hinder the validation process. Inter-laboratory variability perform consistently across different laboratories is crucial but can be challenging due to variations in equipment, personnel, and environmental conditions.
5. Validation often involves understanding and meeting the implicit and explicit needs of users, which can be complex and diverse. Thorough documentation of the validation process, including protocols, acceptance criteria and results, it is essential for demonstrating compliance and reproducibility.
6. Every procedure used under guidelines shall be validated and there must be SOP dealing with validation, verification & acceptance criteria. It is based on National guidelines and standard guidelines ICH Q2 (R1) – Validation of Analytical Procedures: Text and Methodology and others more rigorous approach – parameters, minimum of repeated measurements.

Reviewing the document of method validation is complex procedure and required highly skilled manpower with acceptable predefine limit that is acceptance criteria and work in step by step.

i. Protocol and report-Protocol and report not submitted /protocol not followed report.
ii. Document as required are not consistent, valid, reliable and satisfactory.
iii. Chromatogram peak- Shouldering, Tailing, no printed, integration, Peak shift, Peak consideration,
iv. Raw Data- Analytical Worksheet traceability and data mistake,
v. Overage- No Justification along with references and guidelines in overage,
vi. Column- Using specific column and no peak was observed on testing,
vii. References -No standard and validated References for the Method,
viii. BET calculation limit references for maximum dose in microbiology,
ix. Calculation mistake on parameters-Calculator Error In parameters statistics and formula applied,
x. Solution stability-sample and standard and for next 24 hours freshly prepared reference standard,
xi. Robustness- Flow rate, column temperature, temp. variation was done but not looking mobile phase change and PH.,
xii. Accuracy spiking-placebo as 100 % test concentration.
xiii. Make test concentration and placebo weight constant.
xiv. API-No method validation of combined API.
xv. 80-120% sample preparation-Sample concentration range was not covered,
xvi. Number of theoretical plate (NTP)-Less than 2000 and not justified the reasons,
xvii. Certificate of Analysis (COA) of working standard/ reference standard not found/ tertiary reference standard used,
xviii. Instrument- calibration not documented and found,
xix. References standard expiry date which was less than 6 months,
xx. While testing- No peak observed/ sample does not comply as per method

Method Validation is a complex process. No fixed time duration and no absolute answer is applicable in all cases. It takes longer time than expected as it is research and development, trial and new formulation of the method, required even trained manpower. There is a variation and method robustness parameter is one of the more critical sections of the validation. It must be accepted, validated and verified. It

must meet customer's requirement as well as requires all the process for authorization of method by regulation and approval. Validation needs to be based on experimentally determined acceptance criteria, tested under normal conditions, and with controlled modifications. The sufficient information and data, related substances and degradation pathways, impurity profile, justification, and full-scale method validation requires more time. Method must be easy to work, safe and robust.

The information, data or statistical analysis about API or drug product, the potential impurities, the desired performance parameters or required specifications; all these factors may change and become more stringently controlled as product gets pre- investigation and screening and common technical documentation filing. It is essential for method validation reports thoroughly document the reasons for technical communication why specific test parameters are required for API or drug product? Why specifications are set? Where they are in rationale for selecting specific method conditions? Should be justified.

6. Common Strategies to Prevent Them

- Review all the acceptance criteria defined in the validation protocol against what is known about the method. The use of standard acceptance criteria can be a very useful strategy as long they are used in a scientific manner.
- Carry out a thorough review of all potential interferences when designing the validation protocol.
- Consider the long-term use of a method when designing the validation protocol. What samples will be tested and are there any anticipated changes that could occur to the samples that would affect the potential interferences for the method? If the method is to be used for stability testing, are there any additional requirements, such as a degradation study.
- If any robustness issues are identified, these can be resolved prior to the validation.
- Review the robustness data thoroughly when it is available and ensure that there is a meaningful discussion of its significance in the validation report.
- The samples created for accuracy experiments should be made to be as close as possible to the samples which will be tested by the method. For impurities analysis, it may be necessary to prepare the accuracy samples by using spiking solutions to introduce known amounts of material into the sample matrix.
- Performing replicate measurements instead of replicate preparations.
- For the method to be capable the bias needs to be less than the specification

for the result. Make sure that the acceptance criteria set for accuracy in method validation are compatible with the requirements for the method, and in particular, the specification for the test.

7. Conclusion:

The validation of analytical methods is undoubtedly a difficult and complex task. In pharmaceutical manufacturing method validation is integral part to produce quality medicine. Method validation requires in-depth technical knowledge of product development with regulatory strategy and guidelines for all phases of the review and approval process throughout the product development process. For the regulatory approval national guidelines *Guideline on Analytical Method Validation on Non-Pharmacopoeial Products* must be thoroughly understood and done as per the procedure mention in the guidelines.

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प्रयोगशाला मा सूचना प्रबिधिको प्रयोग र बदलिदो परिवेश

केशब पौडेल –बरिष्ठ केमिस्ट

रासायनिक परीक्षण प्रयोगशालाहरू औषधि निर्माणदेखि वातावरणीय विज्ञानसम्मका विभिन्न क्षेत्रका लागि आधारभूत ढाँचाका रूपमा महत्वपूर्ण छन् । त्यस्ता क्षेत्रमा प्रयोगशालाको परिक्षण प्रतिवेदन मार्फत विभिन्न निर्णय प्रक्रियाहरु र कानुनको पालनामा प्रयोगशालाले उल्लेखिनिय भुमिका खेलेका छन् ।विभिन्न क्षेत्रगत परिवर्तन सगै सटीकता, दिगोपन, र द्रुत गतिको नतिजामा विश्वव्यापी रुपमा माग बढेसँगै यी प्रयोगशालाहरू रूपान्तरणको प्रक्रियामा छन् । यसमा सूचना तथा सञ्चार प्रविधि को मुख्य भुमिका रहेको छ किनकि धेरै क्षेत्रमा यसले गुणत्तरिय प्रभाब पारेको छ । सूचना तथा सञ्चार प्रविधि (ICT) को तीव्र विकासले मानव जीवनका धेरै पक्षमा परिवर्तन ल्याएको छ । सुरुवाती चरणमा टेलिफोन, रेडियो, र टेलिभिजन प्रमुख सञ्चार माध्यम थिए । त्यसपछि इन्टरनेटको विकाससँगै ईमेल, वेबसाइट, र सामाजिक सञ्जालले डिजिटल युगको सुरुआत गर्‌यो । २००० दशकबाट मोबाइल प्रविधिको प्रसारले स्मार्टफोन, मोबाइल एप्स, र वायरलेस इन्टरनेटलाई लोकप्रिय बनायो । २०१० पछिका वर्षहरूमा क्लाउड कम्प्युटिङ, बिग डाटा, र साइबर सुरक्षा जस्ता प्रविधिहरू अगाडि बढे । पछिल्लो चरणमा कृत्रिम बुद्धिमत्ता (AI), ब्लकचेन, इन्टरनेट अफ थिङ्स (IoT), र ५जी प्रविधिले ICT क्षेत्रमा क्रान्ति ल्याएका छन् । यी प्रविधिहरूले शिक्षा, स्वास्थ्य, व्यापार, र सार्वजनिक सेवा क्षेत्रलाई प्रभावकारी र प्रविधिमैत्री बनाउँदै लगेका छन् । यसरी प्रविधिमा भइरहेको विकासले रासायनिक परीक्षण प्रयोगशालाहरूको स्वरूपमा पनि व्यापक परिवर्तन ल्याउने अपेक्षा गरिएको छ । नवीन प्रविधिको विकास, दिगोपनको रणनीति, नियामक परिदृश्यको रूपान्तरण, र सहकार्यात्मक अनुसन्धानले प्रयोगशालाको कार्यशैलीमा महत्वपूर्ण परिवर्तन ल्याइरहेका छन् । यस लेखमा त्यही प्रवृत्तिहरूको समीक्षात्मक विश्लेषण गरिएको छ ।

१. प्रविधिगत नवप्रवर्तन: दक्षता र उत्पादकता वृद्धि

- स्वचालन (Automation), कृत्रिम बुद्धिमत्ता (AI), र रोबोटिक्स को प्रयोगले प्रयोगशालाहरूमा कार्यक्षमता अभिवृद्धि भइरहेको छ ।
- स्वचालित प्रणालीहरू: रोबोटिक प्रक्रिया स्वचालन (RPA) जस्ता प्रविधिहरूले नमूना तयारी, टाइट्रेसन, र डाटा प्रशोधनजस्ता दोहोरिने कार्यहरू छिटो र त्रुटिरहित बनाउन मद्दत गर्छन् ।
- AI र मेसिन लर्निङ (ML): ठूला डेटासेटहरू विश्लेषण, परीक्षण परिणामको पूर्वानुमान, र अनियमितता पत्ता लगाउन यी प्रविधि प्रभावकारी छन् । उदाहरणका लागि, मेसिन लर्निङ मोडेलहरूले रासायनिक प्रतिक्रिया मार्गहरू भविष्यवाणी गरेर अनावश्यक परीक्षण घटाउन सक्छन् ।
- नवीन उपकरण र प्रविधि: Lab-on-a-Chip, 3D-printed microfluidics, र IoT-आधारित

निगरानीले पोर्टेबल, उच्च-क्षमतायुक्त, र वास्तविक समय परीक्षण सम्भव बनाएका छन्।

२. दिगोपन केन्द्रित कार्यशैलीको विकास

- पर्यावरणीय दायित्व ले प्रयोगशालाहरूलाई हरित प्रविधि र परिक्रामी अर्थतन्त्रको अवधारणातर्फ प्रेरित गरिरहेको छ।
- हरित परीक्षण अभ्यास: विलायक पुन: प्रयोग प्रणाली, ऊर्जा-कुशल उपकरण, र विषालु रसायनको विकल्प (जस्तै आयोनिक तरल पदार्थ) ले वातावरणीय प्रभाव घटाएका छन्।
- नविकरणीय ऊर्जा प्रयोग: सौर्य, वायु, र जैविक इन्धन स्रोतहरूको उपयोगमार्फत शून्य कार्बन उत्सर्जन लक्ष्यतर्फ प्रयोगशालाहरू अग्रसर छन्।
- फोहर व्यवस्थापन: रासायनिक उपउत्पादलाई अन्य उद्योगमा कच्चा पदार्थको रूपमा प्रयोग गर्ने प्रविधि अपनाउने प्रवृत्ति बढ्दो छ।

३. विकसित नियामक परिदृश्य

- नयाँ प्रविधिहरूको विकाससँगै नियमनहरू पनि परिमार्जन हुँदै गएका छन्।
- डेटा अखण्डता र ट्रेसबिलिटी: FDA, EU REACH जस्ता निकायहरूले सुरक्षित डेटा व्यवस्थापनमा जोड दिइरहेका छन्। ब्लकचेन प्रविधिको प्रयोगले परीक्षण नतिजा सुरक्षित र पारदर्शी राख्न मद्दत पुर्‍याएको छ।
- द्रुत परीक्षण र स्वीकृति: COVID-19 पश्चात CRISPR-आधारित प्रविधिको शीघ्र अनुमोदनले द्रुत प्रतिक्रिया प्रणालीको विकासमा सहयोग पुगेको छ।
- नयाँ सुरक्षात्मक नियमहरू: PFAS, नानो-सामग्रीहरू जस्ता सम्भावित जोखिमयुक्त तत्वको परीक्षण र सुरक्षित प्रयोग सुनिश्चित गर्न नयाँ कानुनी ढाँचा विकास हुँदैछ।

४. सहकार्य र खुला विज्ञान

- प्रयोगशालाहरूबीचको सहकार्य र ज्ञान साझेदारी प्रवर्द्धनमा जोड
- शैक्षिक संस्था, स्टार्टअप, र सरकारबीच सहकार्य: Horizon Europe कार्यक्रमजस्ता साझेदारी मोडेल विकसित भइरहेका छन्। नेपालमा पनि यस्ता सहकार्यको आवश्यकता छ।
- क्लाउड-आधारित डेटा साझेदारी: विश्वभरका प्रयोगशालाहरू अनुसन्धान डेटा सुरक्षित रूपले साझा गर्न क्लाउड प्लेटफर्महरू प्रयोग गर्न थालेका छन्।

५. आगामी चुनौतीहरू

प्रविधिको विकासले नयाँ अवसरसँगै केही चुनौतीहरू पनि ल्याएको छ यस्ता चुनौतिहरु यस प्रकार छन्:

- साइबर सुरक्षा जोखिम: डिजिटल प्रणालीले डेटा चोरी र ह्याकिङको जोखिम बढाएको छ।
- सीप अभाव: कर्मचारीलाई AI, रोबोटिक्स, र उन्नत विश्लेषण विधिमा तालिम आवश्यक पर्न गएको छ।
- उच्च लागत: साना प्रयोगशालाहरूको लागि प्रविधिमा लगानी गर्नु चुनौतीपूर्ण छ ।नेपाल जस्ता कम विकसित देशहरुले यस चुनौतिको सामना गर्नु पर्ने देखिन्छ।

  यी चुनौती समाधानका लागि सरकारबाट अनुदान, तालिम कार्यक्रम, र AI मा नैतिक नियमको मार्ग दर्शन आवश्यक छन्।

निष्कर्ष

रासायनिक परीक्षण प्रयोगशालाहरूको भविष्य नवप्रवर्तनशील र सम्भावनायुक्त देखिन्छ। प्रविधि, दिगोपन, सहकार्य, र विवेकी नियमनको समन्वयले प्रयोगशालाहरूले वैज्ञानिक अनुसन्धान र औद्योगिक आवश्यकतालाई अझ

प्रभावकारी रूपमा सम्बोधन गर्न सक्छन् । दीर्घकालीन दृष्टिकोणसहित नीति निर्माण र प्रविधिमा लगानीले यी प्रयोगशालाहरूको दिगो भविष्य सुनिश्चित गर्नेछ ।

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Proficiency Testing in Pharmaceutical Quality Control Laboratory

Barsha Shakya-Pharmacy Officer

Introduction

The competency of Pharmaceutical Quality Control (QC) laboratories is critically important for ensuring the quality, safety, and efficacy of medicines. A competent QC laboratory provides accurate, reliable, and timely test results that are the foundation for critical decisions affecting patient health and regulatory compliance. QC labs verify that raw materials, in-process samples, and finished pharmaceutical products meet stringent quality specifications. This prevents the release of substandard or harmful medicines, protecting patients from potential adverse effects. A competent QC lab reduces risks of batch failures, product recalls, and regulatory sanctions, which can lead to significant financial loss, damage to the company's credibility, and serious consequences for public health. The accuracy of laboratory test results depends on the skill of its staff, the equipment and processes it uses, and its systems for controlling quality. Proficiency testing (PT) is an external quality assessment process or system for evaluating laboratory performance by comparing results on blind samples with those of other laboratories. Its main objective is to provide independent demonstrations of laboratory competence. The demand for these activities is increasing globally, and so is no their importance.

Benefits of Participating in Proficiency Testing

Regular participation in PT builds confidence in laboratory results, enhances reputation, and demonstrates regulatory compliance, especially with standards like **ISO/IEC 17025**. PT helps identify inefficiencies, benchmark performance against peers, and uncover improvement areas, leading to cost savings and risk reduction. It also provides independent feedback on staff skills, specimen handling, equipment functionality, and reporting, supporting continuous quality improvement and building trust among clients and regulators. **Without proficiency testing, laboratories would have no objective way to verify that their results are accurate.** Overall, proficiency testing is a key requirement

for accreditation and ongoing evidence of competent, reliable laboratory performance.

Steps for Participating in Proficiency Testing

To participate in proficiency testing, laboratories should first select an accredited provider that meets international standards like **ISO 17043** (which covers competence in proficiency testing providers) and offers appropriate tests for their field (e.g., drug analysis, microbiology, chemical analysis). Labs receive standardized samples upon enrollment, which must be handled and stored properly, following routine procedures to ensure unbiased results. The analysis is performed on the proficiency testing sample just as any real-world sample would be, using the laboratory's usual equipment, methods, and staff, with no special procedures, so the lab's performance is measured under typical working conditions. After analysis, results are submitted to the provider for evaluation against reference values or peer labs. Labs then review feedback: if results are satisfactory, current processes are validated; if not, corrective actions such as recalibrating equipment or retraining staff are implemented. Continuous improvement and regular participation are essential for maintaining testing accuracy and meeting regulatory requirements.

Difference between PT and inter-laboratory comparison

According to ISO/IEC 17025:2017, laboratories must monitor the validity of their test and calibration results by comparing their performance with other laboratories, which can be done through participation in proficiency testing (PT) or inter-laboratory comparisons (ILCs). While PT and ILCs are often used interchangeably, they differ in organization, management, and purpose. An Inter-Laboratory Comparison (ILC) involves two or more laboratories testing the same or similar items under predetermined conditions, which may be informal or formally organized by the laboratories themselves. Proficiency Testing (PT), on the other hand, is a specific type of ILC that is formally organized and managed by an independent third party, often involving a reference laboratory to benchmark participant performance. PT results are formally reported with statistical performance indicators like En or Z scores and are typically required for accreditation and regulatory compliance. In contrast, ILCs are more flexible and may be used for method validation, quality improvement, or collaborative studies. Thus, PT is a subset of ILCs with more rigorous management and formal evaluation to assess laboratory competence.

Common proficiency testing challenges

Common proficiency testing challenges in laboratories include sample handling and storage issues (like contamination, temperature exposure, and mislabeling), difficulties interpreting PT results due to unclear feedback or distinguishing errors from normal variation, and meeting regulatory or accreditation requirements, such as tracking deadlines and managing documentation. Cost constraints and inconsistent staff training also pose problems. Solutions involve following strict storage protocols, using digital tracking systems, maintaining organized records, prioritizing required tests, seeking collaborative or sponsored PT programs, and ensuring regular staff training and supervision to minimize errors and improve consistency.

Proficiency Testing at the National Medicines Laboratory (NML)

The role of NML as a **National Drug Control Laboratory** significantly enhances its commitment to quality assurance through proficiency testing. At the National Medicines Laboratory (NML), proficiency testing is a key part of the quality assurance program. Over the last six years, NML has participated in several international proficiency testing programs with satisfactory results. Additionally, NML integrates PT into its **Quality Manual**, which outlines the procedures and policies for maintaining laboratory standards. The laboratory follows a **Standard Operating Procedure (SOP)** that ensures consistent implementation of PT activities and defines the steps for addressing any non-conformities. Furthermore, NML has an **Annual PT Plan** that sets out the schedule for PT participation, helping ensure that all necessary tests are conducted on time.

Conclusion

Proficiency testing is an essential tool for ensuring the reliability, accuracy, and competence of laboratories. By incorporating proficiency testing into their quality assurance programs, laboratories can improve their performance, enhance their credibility, and meet the expectations of regulatory bodies and clients. In an increasingly competitive and regulated industry, proficiency testing remains a cornerstone for excellence in laboratory operations.

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SUMMARY OF PARTICIPATION IN PROFICIENCY TESTING SCHEME BY NML

From year 2076 to 2081

SN.	Name of PT Provider	Test Parameter	Results (Z/ Value)
1	United States Pharmacopoeia (ILC)	Dissolution test of Sulfamethoxazole and Trimethoprim tablets by HPLC	Sulfamethoxazole=1.4 (satisfactory) Trimethoprim= -1.6 (satisfactory)
2	NSI Solution	Identification of Acetaminophen solution by UV	satisfactory
3	NSI Solution	Assay of Caffeine citrate by HPLC	0.210 (satisfactory)
4	European Directorate for the Quality of Medicines and Healthcare (EDQM)	Dissolution test of Furosemide tablet by HPLC	-0.8 (satisfactory)
5	European Directorate for the Quality of Medicines & HealthCare (EDQM) (PTS237)	Dissolution test of Fexofenadine Hydrochloride tablet by HPLC	1.2 (Acceptable Result)
6	MUHAS Pharm R & D Laboratory Muhimbili University of Health and Allied Sciences (PT Round 11)	Assay and Disintegration test of Amoxicillin Capsules	Assay = 0.4 (Satisfactory)

Effective Technique for the Management of Reference Standards

Purna Shrestha – Quality Control Inspector

In the pharmaceutical industry, maintaining standards of quality control and assurance is vital to guarantee the safety and effectiveness of medications. Reference standards play a critical role in analytical laboratories, pharmaceutical quality control and research field. It provides a reliable basis for assessing the quality, safety, and efficacy of pharmaceutical products. These substances are highly purified and precisely characterized, making them crucial for conducting accurate analytical tests, verifying drug identity, potency, purity, and supporting method validation and regulatory compliance. Effective techniques for managing reference standards are essential to maintain the quality and traceability of laboratory operations.

Laboratories should establish a clear standard operating procedure to define the life cycle from receipt, qualification, storage, use or handling, re qualification and disposal. It is better to use centralized inventory systems to track each standard's receipt, usage, storage, and expiry. For the consistency and compliance, it must address procedures for standards and include detailed instructions for labeling, documentation, and traceability. After the receipt of reference standards, it should undergo controlled registration with unique identification code following the batch number, source, potency, storage requirements and certificate of analysis (COA) must be recorded. Before its release for use, the COA, validity and safety Data Sheet should be reviewed and approved.

Qualification and verification of secondary standards are critical. These should undergo identity and assay testing against certified primary standards to confirm their suitability. The outcomes must be documented in a qualification report, and the standard's expiry or retest dates should be defined based on available stability data. This ensures that all standards used in the lab are scientifically justified and compliant with regulatory expectations. After qualification, working reference standards must be filled into containers within a controlled environment, and small quantities should be securely sealed in suitable closed containers

to minimize multiple environmental exposure and maintain their quality. Proper storage conditions play a vital role in preserving the integrity of reference standards. Common conditions include refrigeration at 2–8°C, freezing at -20°C, or store in air-lock container with silica, or as per the storage requirement. The packaging bottle of reference standards should be securely sealed with seal tape after each use to preserve its integrity and lifespan. Dedicated storage areas should be used, access must be restricted, and all equipment should be calibrated regularly. Clear labeling and identification are necessary for preventing mix-ups and ensuring traceability. Every container should bear a label that includes the name of the standard, lot or batch number, unique ID, potency on an as-is basis, recommended storage conditions, and relevant dates such as the date of receipt and expiry or retest date. Proper labeling supports efficient usage and audit readiness.

Inventory control and usage tracking systems should be established to monitor how and when reference standards are used. A logbook must record the date of use, quantity used, analyst's name, and the purpose of use (such as assay or dissolution). Expiry and re qualification management is another essential aspect. Laboratories should regularly review their reference standard inventory for approaching expiry or stability concerns. Standards that are still suitable for use can be re-qualified following proper protocols otherwise; they must be discarded. A defined disposal procedure is necessary to handle expired or unqualified standards. Disposal should be carried out according to SOPs, with documentation including the reason for disposal and QA approval. This ensures transparency and regulatory compliance. Personnel training is fundamental to the entire process. Analysts and quality control staff must be trained on SOPs, handling procedures, and qualification techniques. Training records should be maintained and regularly updated to reflect current knowledge and competency levels.

Finally, auditing and quality oversight reinforce the robustness of reference standard management. Internal audits should evaluate all aspects, including logs, qualification data, and storage conditions. The quality assurance (QA) must play an active role in overseeing and approving key activities such as standard qualification, expiry extensions, and disposal decisions. Laboratories can ensure the accurate, safe, and compliant use of reference standards with these structured practices in place.

How to check Current Lot of primary reference standards

1. **Visit the Official Website**
   - Go to the website of the certifying body (e.g., USP, EP/EDQM, BP, WHO, IP).

- They usually have a "Reference Standards Catalog" or "Current Lot List" section.

2. **Search for the Reference Standard Name or Catalog Number**
   - Enter the name (e.g., Caffeine RS) or the catalog number.
   - It will show the current valid lot number.
3. **Check the Certificate of Analysis (CoA)**
   - Download the latest CoA from the website.
   - The CoA tells you:
     - Lot number
     - Purity
     - Expiry/validity date
     - Storage conditions
     - Any special handling instructions
4. **Cross-check with In-house Stock**
   - Verify that the lot you are using in your lab matches the current valid lot.
   - If your lot has expired or been replaced by a new lot, you must qualify the new lot before using it.
5. **Sign up for Notifications (Optional)**
   - Some pharmacopoeias like USP allow you to subscribe for email alerts when new lots are issued.

For Indian Pharmacopeial reference standards go to the official website of the Indian Pharmacopoeia Commission https://www.ipc.gov.in. On the IPC homepage, look for the Product and service and select IP reference substance and impurities then choose list of IP reference standard and impurity list available in IPC. Check for the Latest Information on Available Lots, if you cannot find the information directly on the website, you can contact the IPC directly. Always keep printed or digital copies of the CoA for each batch you use because it is required during audits and regulatory inspections.

References:

1. ISO 17034:2016 General requirements for the competence of reference material producers.
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3. https://www.usp.org/sites/default/files/usp/document/help/how_to_use_rs.pdf
4. https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs943-annex3-establishmentmaintenance-distribution-chemica-reference-substances.pdf?sfvrsn=71064286_0
5. https://www.edqm.eu/en/ph-eur-reference-standards-purpose-and-use

Quality Control in Microbiology Laboratory

Sushmita Marasini - Pharmacy Officer

Microbial contamination of Pharmaceuticals is a major risk that is inherent in a pharmaceutical manufacturing process which directly impacts product integrity, quality and patient safety.

Microbiological quality control is an essential part of the pharmaceutical manufacturing process to ensure product safety, efficacy, and purity by detecting and managing microbial contamination throughout production. Microbiological quality control is critical because it ensures that pharmaceutical products are free from harmful microorganisms such as bacteria, fungi, and viruses. Contaminated product risk patient infections, reduced efficacy leading to treatment failure.

Microbiological quality control is very crucial especially for parenteral preparation as such preparation are directly administered to patients' body where inferiority in quality can lead to serious health hazard. Therefore, to ensure the safety of each of these products prior to patient administration, pharmaceutical companies must adhere to strict government regulations regarding quality control. Maintaining and following a robust quality control program is integral to quality standards and meeting regulatory requirements.

To ensure product safety, pharmaceutical companies must be versed in the important role of microbiological testing in product research and development, process validation, manufacturing, and quality control. They must safeguard the quality and safety of their products by thoroughly testing raw materials, equipment, environmental surfaces, and final preparations for microbial contaminants that may have been introduced inadvertently during or subsequent to the manufacturing process.

Though there are various strict national and international guidelines and regulations that mandate robust microbiological quality control procedures, failing to adhere to these standards can result in product recalls, regulatory penalties and loss of public trust.

A Comprehensive multi step approach is required to ensure microbiological quality of products and minimizing contamination risks so that the products meet safety and regulatory standards:

- Testing Raw material
- Environment monitoring
- Aseptic Processing and clean room control
- Terminal sterilization validation
- Microbial Enumeration and identification
- Sterility testing
- Bacterial Endotoxin test/Pyrogen Testing
- Preservative Efficacy testing
- Use of Validated methods
- Rapid Microbiological techniques
- Equipment and Process control
- Adherence to Regulations

Being a National Quality control lab National Medicine Laboratory is carrying out Microbiological quality control test for finished pharmaceutical products to provide an assurance that they meet the established quality standards and is safe for their intended use. For Finished Pharmaceutical products microbiological quality control test recommended by the official pharmacopoeia are carried out by NML to ensure product quality and safety. Below mentioned test parameter are routinely performed by National laboratory for finished pharmaceuticals as per regulatory requirements.

1. **Sterility Testing (USP <71>, IP 2.2.11)**

Purpose: To confirm that a product is completely free of viable microorganisms.

- Method:
  - Membrane Filtration Method: The product is filtered through a 0.45 µm filter, which captures any microorganisms, followed by incubation in suitable culture media.
- Incubation Conditions:
  - Bacterial media: 30-35°C for 14 days
  - Fungal media: 20-25°C for 14 days
- Acceptance Criteria: No growth in any of the test containers.
- Controls: Positive Product controls to confirm no interference, Positive and negative controls to validate test conditions.

2. **Bacterial Endotoxin Testing (BET) - LAL Test (USP <85>, IP 2.2.3)**

Purpose: Detect and quantify endotoxins from Gram-negative bacteria, which are highly pyrogenic.

- Methods:
  - Gel Clot Method: Qualitative test based on gel clot formation.
- Limit Calculation: Based on product dose and endotoxin limit as per Pharmacopoeia.
- Acceptance criteria: No gel clot in any of the test tubes.
- Controls**:** Use positive product controls to confirm no interference, Positive and negative controls to validate test conditions.

3. **Microbial Enumeration Test/Microbial Limit Test:** USP <61> (Microbial Enumeration Tests) and USP <62> (Tests for Specified Microorganisms) IP 2.2.9 Microbial Contamination in Nonsterile Products)

The Microbial Limit Test (MLT) is a critical part of the microbiological quality control of non- sterile pharmaceuticals, ensuring that they are within acceptable microbial contamination levels.

- Total Microbial Count: Determine the total number of aerobic bacteria and fungi (yeasts and molds) present.
- Absence of Specific Pathogens: Confirm the absence of specified harmful microorganisms like *E. coli*, *Salmonella spp.*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus* in products where these would pose a health risk.

  Methods:

  Plate Count Method: Pour plate, spread plate, or membrane filtration.

  Incubation Conditions**:**

- Bacteria: 30-35°C for 3-5 days.
- Fungi: 20-25°C for 5-7 days.

4. Microbiological Assay of Antibiotics: (USP<81>Antibiotics-Microbial Assays, IP 2.2.10):

Antibiotic assays are critical quality control tests used to confirm the potency and efficacy of antibiotic-containing pharmaceutical products.

Method: Cylinder-Plate (Agar Diffusion) Method

Principle:

- An antibiotic diffuses from a well or cylinder into an agar medium seeded with a sensitive test organism.
- The zone of inhibition around the well is measured to determine the potency of the antibiotic.

  Microbiological quality control is a foundational element of pharmaceutical manufacturing and quality control, safeguarding patient health, ensuring regulatory compliance, maintaining product quality and business credibility. Without it the risks to public health and industry integrity would be significant.

References:

1. WHO TRS, No. 961, Annex 6 2011, WHO GMP for sterile pharmaceutical products
2. https://www.researchgate.net/publication/286554163_Microbiological_quality_of_pharmaceutical_products
3. United states Pharmacopoeia 2024
4. Indian Pharmacopoeia 2022

Importance of HPV Vaccines in HPV Related Cancer and Lot Release

Sachita Joshi –Senior Quality Controller

HPV (Human papillomavirus) related cancer, the availability of HPV vaccines and quality assurance of vaccines by regulatory authority before it reaches to public is of a great concern to prevent from these diseases.

About the HPV

It is a group of more than 200 related non-envelop DNA viruses. HPV can cause benign tumors called papilloma or warts, some of which can lead to the development of cancers. The route of transmission is sexual or vertical transmission (mother to child during childbirth). There are mainly two types of HPV with high and low risk of cancer. Low-risk, non-oncogenic types are HPV 6 and 11, which do not cause cancer but do lead to up to 90% of genital wart diagnoses. **High-risk**, oncogenic types are **HPV 16 and HPV 18**, associated with persistent infections and are recognized as oncogenic and responsible for 70% of all cervical cancer worldwide. HPV related cancers and disease shows 99.7% of cervical cancer, 90% of anal cancers particular in individual with HIV and men who have sex with men, 25% of vulval cancers, 50% of penile cancers and 60% of oropharyngeal cancers.

Global data on cervical cancer and global strategy on elimination of cancer

Cervical cancer is the 4th most common cancer in women, causing over 300,000 deaths. 80% of cervical cancer cases occur in women who are under or never screened. 90% of cervical deaths occur in low and middle-income countries. Cervical cancer has a long precancerous phase with cytological changes that progress through different grades, such as HPV infection of squamous epithelial cells (koilocytotic), cervical intraepithelial, and ultimately invasive carcinoma. There is a long latency period during which precursor lesions such as cervical intraepithelial neoplasia (CIN) can be detected with cervical screening tests. In most cases, the immune system clears HPV. However, 50% of people will develop antibodies against the virus following infection, but it may take as long as 18 months to seroconvert. Regardless, over 80% of HPV infections are transient, asymptomatic, and resolve spontaneously.

Persistent HPV infection can cause abnormal cells to develop on the cervix, which leads to cervical cancer if left untreated. Risk factors for HPV related cancers are lack of vaccination, gender and sexual practices, smoking, and immune-compromise state. The disease is largely preventable. The economic burden of HPV related diseases is related to the Cost related screening, diagnosis and treatment, and preventive action vaccination.

"The Global Strategy for the Elimination of Cervical Cancer," with an intermediate 2030 triple-intervention strategy known as the 90–70–90 targets in 2019. The triple targets to achieve are 90% of adolescent girls fully vaccinated against HPV by age 15, 70% of women screened for cervical cancer at age 35 and 45, and 90% of women with invasive cervical cancer or precancer of the cervix treated. The cervical cancer burden can be reduced with vaccination and screening. The HPV vaccine was developed by Ian Frazer in Queensland, Australia. The vaccine contains no viral DNA or RNA and, therefore, is non-infectious and non-oncogenic. When injected into humans, it produces a large number of neutralizing antibodies that are HPV type-specific and at far greater numbers than achieved from natural infection. HPV vaccines protect against the most common oncogenic strains (types 16, 18, 31, 33, 45, 52, 58) and those responsible for genital warts (6, 11). The primary target population eligible for vaccination are girls aged 9-14 years before they become sexually active. More than 80% coverage in girls will reduce the risk of HPV infection for boys. It should be included in national immunization programs. The secondary target population is females aged >15 years, Boys and older males, Men who have sex with males only if feasible and affordable. Another target population can be the Special population with immune-compromised women and men living with HIV, children and adolescents who have faced sexual abuse.

HPV vaccines in Nepal

The HPV vaccines registered in regulatory authority of Nepal are "the bivalent **Cervarix** vaccine (type16,18)", approved from EMA, **Cecolin** (type 16, 18)", which is WHO PQ vaccine from China, "**Walrivax** bivalent vaccine (type 16 and type 18**)**, China recently got WHO PQ, "**Gardasil 9**" from Merck covering 9 types of HPV types (6,11,16, 18, 31, 33, 45, 52, 58). The HPV type 16 and 18 is responsible for oncogenic activity so bivalent vaccine can be effective for the prevention of cervical cancer. The WHO Strategic Advisory Group of Experts on Immunization (SAGE) concluded that a single-dose Human Papillomavirus (HPV) vaccine is comparable to 2-dose schedules in its efficacy (WHO 8). In immunogenicity studies, HPV16/18 antibody seropositivity rates were high among all HPV-vaccinated participants. Antibody levels were significantly lower with one dose compared

to two or three doses, but levels with one dose were stable and sustained to 11 years post-vaccination (systematic review). Additionally, WHO has announced that a fourth WHO-prequalified human papillomavirus (HPV) vaccine product, Cecolin has been confirmed for use in a single-dose schedule and this helps simplifies the vaccination process with less expensive, easy to administer with broader coverage rates, and ideally suited for low middle income countries.

Lot release of vaccine

For the quality assurance of vaccines regulatory authorities ensure the quality of vaccines during registration process based on reliance. Once it is registered, vaccine can be used within the country and has to go through lot release process for every batch of vaccine supplied. The National Medicine laboratory organogram has a Biological section under which there is a vaccine unit and Pharmacology and toxicology unit. The vaccine unit is responsible for the lot release of vaccines. NML has been doing lot release for both WHO PQ and non-PQ vaccines that are requested by the Department of health services. NML does not have its own guideline on lot release of vaccines. Therefore, it has been doing the lot release based on the WHO guideline for lot release of vaccine WHO TRS 978. NML has developed standard operating procedure (SOP) for lot release of vaccines based on the guideline.

There are some considerations for establishing lot release procedures by the procuring NRA/NCL. In cases where a lot has already been released by another NRA/NCL, it may be possible to accept that lot for release based on the existing release certificate. Acceptable processes may range from a list of countries acceptable to the importing country, through to Mutual Recognition Agreements. The establishment of mutual recognition agreements is a legal approach. Many NRAs/NCLs establish the practice with the aims to enhancing international regulatory cooperation to maintain high standards of product safety and quality, facilitating the reduction of the regulatory burden for NRAs/NCLs and manufacturers and improving the free flow of vaccines and accessibility globally.

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4. The Lancet Oncology. HPV vaccination in south Asia: new progress, old challenges. Lancet Oncol. (2022) 23:1233.

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8. WHO TRS 978 Annex 2. Guidelines for independent lot release of vaccines by regulatory authorities.

Good Documentation Practices in Quality Control Laboratory

Reshma Shakya- Pharmacy Officer

Good Documentation Practice (GDP) is a systematic procedure of preparing, reviewing, approving, issuing, recording, storing and archiving of documents. GDP describe standards by which documents are created and maintained. The aim is to maintain the integrity, accuracy, and traceability of records, ensuring that they reflect exactly what was done, when was done, and by whom. They ensure that all data and records are accurate, consistent, and trustworthy, serving as the backbone of regulatory compliance, product quality, and patient safety. By following GDP, organizations can demonstrate compliance with national and international regulatory requirements, support effective quality control, and ensure that products meet safety and efficacy standards. It also helps prevent errors, enables thorough investigations during deviations, and provides clear evidence during audits and inspections. Ultimately, it upholds product quality and protects patient safety by fostering transparency, accountability, and trust in documented processes.

Principle of GDP

Good documentation requirements for manual and electronic records include the following, as applicable; **ALCOA**: A commonly used acronym that all records and data should be **attributable, legible, contemporaneous, original and accurate.**

ALCOA-plus: A commonly used acronym for "attributable, legible, contemporaneous, original and accurate" data, which puts additional emphasis on the attributes of being **complete, consistent, enduring and available.**

Requirements of GDP in ISO/IEC 17025:2017

In ISO/IEC 17025:2017, several clauses collectively establish the foundation for Good Documentation Practices (GDP). **Clause 7.5 (Technical Records)** requires laboratories to retain original data, observations, and calculations at the time they are made. Any amendments made to technical records should be tracked to previous version and should be signed, dated, and justified. **Clause 8.3 (Control of Documents)** requires laboratories to establish and maintain control over internal and external documents. The laboratory must ensure documents are reviewed and approved

for adequacy prior to use, kept up-to-date, and accessible where needed. Changes must be controlled and tracked to prevent the unintended use of obsolete documents, with clear identification of the current version and appropriate authorization. **Clause 8.4 (Control of Records)** mandates that all records be stored securely, retained for defined periods, and protected against unauthorized access or alteration.

21 Code of Federal Regulations (CFR)

In 21 CFR, raw data refers to the original records and first observations captured during the performance of an activity, whether recorded manually or electronically. It must be complete, accurate, and preserved without alteration, as it forms the foundation for final reports and decisions. All raw data including laboratory test results, manufacturing data, must be retained and available for review. If data is captured electronically, it falls under 21 CFR Part 11, which establishes rules for electronic records. Part 11 requires that electronic records must be as trustworthy and reliable as paper records, with system validation, secure user access, complete audit trails, and properly linked electronic signatures. Raw data stored electronically must be protected against unauthorized changes and must maintain its integrity throughout its lifecycle.

Documentation Practices Rules

1. If it is not written down it did not happen

2. If it is not written down correctly, it did not happen as performed

Documentation Practices Data Entry

For each task, a detailed record should be maintained, clearly outlining what the task was, how it was carried out, when it was performed, and who was responsible for completing it. It is essential to ensure that all data recorded is accurate and up to date. Any errors identified must be corrected immediately to maintain the integrity of the records. Accountability should be upheld at all times, with each individual taking responsibility for their actions and the information they record. All documentation should be complete, with no blank spaces left, to prevent ambiguity or misunderstandings.

Documentation Practices Correcting Mistakes

Mistakes should be corrected by the individual who made them. If that person is unavailable, the supervisor can make the correction. To correct an error, draw a single line through the mistake, then make the correction next to it, note the reason for the error. The person making the correction should initial and date it. If an error is discovered at a later time, it should still be corrected and initialed or dated on the day the correction is made, backdating is not allowed. It's important to correct mistakes without removing the original data.

Analytical Worksheet in QC Laboratory

The analytical worksheet is used by the analyst to record detailed information about the sample, including the test procedure, calculations, and the results obtained. It serves as a key document

in which raw data must be attached. A separate analytical worksheet shall be maintained for each sample to ensure clear and traceable documentation.

Content of Analytical Worksheet in QC Laboratory

The analytical worksheet must contain comprehensive information to ensure accurate and traceable documentation. This includes the registration number of the sample, complete page numbering with the total number of pages, and key dates such as the request date, start of analysis, and completion date. It should also include the name and signature of the analyst, a detailed description of the sample, references to the relevant test methods, specifications and acceptance limits. Details of the test equipment and reference substances used must be recorded. The results of the system suitability test should also be documented. The worksheet should list the reagents and solvents employed, the results obtained, and an interpretation of those results along with the final conclusions. Any deviations or additional remarks should also be noted. All values must be entered immediately on the analytical worksheet, and any graphical data should either be attached directly or traceable to an electronic record. Once completed, the analytical worksheet must be signed by the analyst, verified, and signed by the supervisor.

Common GDP Errors

Common errors in Good Documentation Practices (GDP) include use of outdated or uncontrolled forms for data recording and creating illegible or unclear documentation. Other frequent issues are failing to enter raw data into worksheets at the time of generation, leaving study forms incomplete, making corrections improperly or excessively, and providing insufficient explanations for data changes, including how the correct entries were confirmed.

Conclusion:

Good Documentation Practice ensures that all laboratory activities are accurately recorded, traceable, and compliant with regulatory standards. Proper documentation from analytical worksheets to raw data handling supports transparency, enables accountability, and ensures the validity of results. Avoiding common GDP errors and following structured correction procedures further strengthens data credibility.

Reference:

- World Health Organization (WHO) good practices for pharmaceutical quality control laboratories, Annex 1
- International Organization for Standardization (ISO). *ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories*.
- United States Pharmacopeia (USP), USP 2024, General Chapter <1029>, Good Documentation Guidelines
- U.S. Food and Drug Administration (FDA). Code of Federal Regulations (CFR), Title 21, Parts 58, Part 11

Ensuring excellence: Microbiological Good Laboratory Practices

Nisha Shrestha-Pharmacy Officer

Pharmaceutical microbiology laboratories may be involved in: sterility testing; detection, isolation, enumeration and identification of microorganisms (bacteria, yeast and moulds) and testing for bacterial endotoxins in different materials (e.g. starting materials, water), products, surfaces, garments and the environment; and assay using microorganisms as part of the test system. This process aims to safeguard the integrity of pharmaceutical products and protect public health. Good Practices in a microbiology laboratory consist of activities that depend on several principles: aseptic technique, control of media, control of test strains, operation and control of equipment, diligent recording and evaluation of data, and training of the laboratory staff in related competencies. USP <1117> outlines best practices for microbiological labs, providing a framework that ensures consistent, accurate, and reliable results. Some of the key activities that can be adopted for Microbiological Best Laboratory Practices are: Control of Media, Maintenance of Microbiological Cultures, Use and Control of Equipment, Appropriate Lab Layout, Control of environment, Sample Handling and Labeling, Training and Competency, Aseptic Techniques, Good Documentation Practices (GDP), Data integrity of microbiological data, Maintenance of Laboratory Records, Microbiological Risk Assessments, and Disposal of contaminated waste etc.

Control of Media: Culture media are the basis for most microbiological tests. Safeguarding the quality of the media is therefore critical to the success of the microbiology laboratory. Media preparation, proper storage, and quality control testing can ensure a consistent supply of high-quality media. It is important to choose the correct media or components in making media based on the use of accepted sources or references for formulas.

Maintenance of Microbiological Cultures: Biological specimens can be the most delicate standards to manage because their viability and characteristics are dependent on adequate handling and storage. Cultures for use in compendial tests should be acquired from

a national culture collection or a qualified secondary supplier and have documented equivalency to relevant ATCC strains. They can be acquired frozen, freeze-dried, on slants, or in ready-to-use forms. Confirmation of the purity of the culture and the identity of the culture should be performed before its use in quality control testing. Working stocks should not normally be sub cultured. Usually not more than five generations (or passages) from the original reference strain can be sub cultured.

Use and Control of Equipment: Use Calibrated, Validated, and Qualified Equipment in well-designed laboratory. Routine preventive maintenance of equipment is critical to ensuring that the equipment is in good operating condition and maintains its reliability.

Appropriate Lab Layout: Laboratory layout and design should carefully consider the requirements of good practices in a microbiology laboratory and laboratory safety. Lab should use materials that are easy to clean and disinfect, reducing contamination risks. Separate air-handling systems for labs areas are required, with appropriate air quality and environmental controls. Entry should be limited to authorized personnel who are trained in procedures, area use, restrictions, and containment requirements. WHO good manufacturing practices (GMP) for sterile pharmaceutical products requires that sterility testing should be carried out and specifies requirements for sterility testing. The sterility testing should be carried out within a Grade A unidirectional airflow protected zone or a biosafety cabinet (if warranted), which should be located within a clean room with a Grade B background.

Control of environment: It is important to consider that microbial contamination of samples, which leads to false-positive results, is always possible unless careful aseptic precautions are taken. Facilities should be designed so that raw material and excipient sampling can be done under controlled conditions, including proper gowning and the use of sterilized sampling equipment. **Sample Handling and Labeling:** Samples submitted to the microbiology laboratory should be accompanied by documentation detailing source of the sample, date the sample was taken, date of sample submission, person or department responsible for the submission, storage conditions and any potentially hazardous materials associated with the sample. All microbiological samples should be taken using aseptic techniques, including those taken in support of non-sterile products. **Training and Competency:** Each person engaged in each phase of pharmaceutical manufacture should have the education, training, and experience to do his or her job.

Aseptic Techniques: It is a reference to actions taken to prevent microbial contamination. It is accomplished through practices that maintain

the microbe count at a minimum. Aseptic technique is not of only hand washing, garbing/ gowning, the use of disinfectants, sterile 70 % IPA, and sterile equipment it must also include thinking ahead, planning, and the implementation of preventive measures. Not only are these things important in the cleanroom where compounding occurs, but they must also be considered as part of the work practices in the microbiology lab. All microbiological samples should be taken using aseptic techniques, including those taken in support of non-sterile products. The areas and methods of transport of samples should be designed to minimize contamination.

Good Documentation Practices (GDP): Documentation (either manually or by an electronic laboratory management system should be sufficient to demonstrate that the testing was performed in a laboratory and by methods that were under control.

Maintenance of Laboratory Records: Proper recording of data and studies is critical to the success of the microbiology laboratory. The overriding principle is that the test should be performed as written in the SOP, the SOP should be written to reflect how the test is actually performed, and the laboratory notebook/worksheet should provide a record of all critical information needed to reconstruct the details of the testing and confirm the integrity of the data. **Data integrity of microbiological data:** To enhance data integrity and minimize subjectivity, alternative methods like automated plate readers and high-resolution imaging are increasingly employed. These technologies can standardize data capture and improve reproducibility. However, they also present specific challenges, including; Difficulty detecting colonies embedded within agar (as in pour plates), Inaccurate enumeration of satellite colonies, Inability to distinguish overlapping colonies, Misidentification of particles as colonies, and Variability in interpretation of images between individuals. Emerging automated enumeration methods that use image stacking over time to track colony growth may help address some of these limitations.

Microbiological Risk Assessments: Microbiological risk assessment is performed for sterile and non-sterile manufacturing activities to establish the microbial risks and their impact on the quality of the medicinal products. A microbiological risk assessment can be beneficial and provide information to assist in decision-making about the impact of microbiological quality. Some examples of when a microbiological risk assessment might be used are: 1) elevated bio burden counts (but within specification); 2) growth of atypical colonies after enrichment on selective agar plates for compendium-specified microorganisms; 3) exceeded alert/action levels; and 4) identification of a recovered species of

concern. Hazard Analysis Critical Control Point (HACCP) methodology is successfully applied by pharmaceutical companies to reduce risk of microbial contamination through identifying areas in the process and types of raw materials and equipment that are at high risk of being contaminated with microorganisms. Assessment of the critical control points and the ability to consistently monitor them for any process makes it better for preventive applications than reactive.

Disposal of contaminated waste: The procedures for the disposal of contaminated materials should be designed to minimize the possibility of contaminating the test environment or materials. It is a matter of good laboratory management and should conform to national/international environmental or health and safety regulations.

Indeed, while best practices in microbiological quality control (QC) are essential for ensuring the safety and efficacy of pharmaceutical products. Laboratories in context of our country often face various challenges during routine QC testing activities. These challenges can arise from technical, operational, and environmental factors. Below are some of the common challenges:

- Contamination risk during testing due to inadequate aseptic techniques, Contaminated testing equipment, Environmental factors due to inappropriate layout (e.g., airborne particles or microbial growth in labs)
- Proper Storage, Preservation and Handling of American Type Culture Collection (ATCC culture) is challenging due to their sensitive nature.
- Lack of training and workshop regarding the pharmaceutical microbiological quality control
- **Time-consuming test method** leading to **delays in report release**
- **Lack of adequate budget allocation**

Microbiological quality control is a cornerstone of pharmaceutical manufacturing, ensuring that products are safe, effective, and free from harmful contaminants. Adherence to Microbiological Best Laboratory Practices, as outlined in USP <1117> and WHO guidelines, is critical for achieving reliable and reproducible test results. Key practices such as strict aseptic techniques, proper media and equipment control, rigorous documentation, effective training, and thorough environmental monitoring serve to minimize variability and enhance data integrity. By embedding these practices within a robust quality management framework, pharmaceutical laboratories can uphold high standards of microbiological safety and regulatory compliance, ultimately safeguarding public health.

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Waste Disposal Methods in Pharmaceutical Laboratory

Samjhana Suwal-Pharmacy Officer

Introduction

Effective management of laboratory waste in pharmaceutical settings is a critical concern due to the hazardous nature of the waste, which poses risks to human health, animals, and the environment. Additionally, it is essential to comply with national and international regulatory standards. A wide variety of waste is generated in pharmaceutical laboratories, including paper, bottles, hazardous chemicals, reagents, and more. Common types of laboratory waste include: lab prepared solutions (e.g., standard/sample solution, mobile phase, buffer solution, volumetric solutions), expired chemicals & reagents, expired reference standard & drug control sample, leftover drug sample, broken laboratory glassware (e.g., volumetric flask, pipette, conical flask), empty chemical container, gloves, mask, vials, ampoules, contaminated micropipette tips & media, expired growth media, chemically contaminated waste water, corrugated box, duplex & paper.

Proper disposal involves segregation, labeling, secure storage & applying specific disposal methods based on waste classification.

1. Steps in Laboratory Waste Disposal

1.1 Identification and Classification:

Wastes are identified and classified into categories such as chemical, biological, hazardous, and non-hazardous to ensure appropriate handling and disposal.

1.2 Segregation:

Different waste types must be segregated & collected into designated containers (e.g., sharps in puncture-resistant containers; separate container for chemical, biological & hazardous waste).

1.3 Labeling:

Containers must be clearly labeled with the waste type, date of accumulation and associated hazards (if any).

1.4 Storage:

Waste containers must be stored safely and securely away from potential hazards and in compliance with safety regulations.

1.5 Disposal:

Appropriate disposal methods for each waste type must be employed such as incineration, neutralization or chemical decomposition.

2. Specific Waste Disposal Methods

2.1 Disposal of lab generated solutions

Solution should be segregated based on characteristic (e.g., organic/inorganic, acid/base, corrosive/noncorrosive). pH of the solution should be measured & then neutralized using acid or base (if waste is acidic, neutralize it with base and if it is basic, neutralize it with acid). After neutralization, it can be disposed into the sink with continuous flow of water. For solution containing organic solvent or corrosive, dilute 1:10 with water or significantly diluted with water before disposal under flowing water.

2.2 Disposal of Expired chemicals & reagents

These should be segregated & stored separately & consult Material safety data sheet (MSDS). Liquid can be diluted 1:10 with water or significantly diluted with water & disposed under continuous flow of water. Solid waste should be stored in a clearly labeled container until final disposal. Factors like flammability, reactivity, corrosivity & toxicity should be considered while determining disposal methods. Disposal methods like secure landfill, incineration, thermal treatment (e.g., pyrolysis method) or chemical treatment can be used for disposal of hazardous chemicals.

2.3 Disposal of Expired reference standard, expired drug control sample, leftover drug sample

WHO Guidelines for the safe disposal of expired drugs 2006 has recommended various methods for the safe disposal of expired drugs. Drug take-back programs are preferred. Likewise unnecessary purchase of reference standard should be avoided. Antineoplastics & controlled substances should be disposed via encapsulation, inertization or high-temperature incineration (>1200°C). Other drug waste can be disposed in engineered landfill, medium temperature incineration (>850°C) or chemical decomposition (ion exchange, precipitation, oxidation & reduction, neutralization).

2.4 Disposal of Broken laboratory glassware

Appropriate personal protective equipment (PPE) should wear when handling the broken glassware. Non-contaminated glassware must be placed in a small puncture proof, double-lined cardboard box & should not be overfill, only fill ¾ of the container. Contaminated glassware; sharps, needles, syringes;

mercury-containing materials; biological materials; chemicals; radioactive materials should never be disposed of in a broken glass box.

Glassware containing chemicals or hazardous waste is considered hazardous waste and must be collected carefully in a puncture-proof container and disposed of as hazardous waste.

Glassware contaminated with biological materials must be decontaminated using disinfectant like sodium hypochlorite prior to disposal.

Any broken or disposable glassware contaminated with biological materials must be disposed as a contaminated sharp (similar to a needle or other sharp) and must be placed directly into a sharps container and disposed with biological waste.

2.5 Disposal of Empty chemical container

If the chemical is not acutely hazardous, triple rinsing of container should be done with water or solvent capable of removing the original container. If the rinsing solvent is hazardous (e.g. acetone, methylene chloride), the rinsate must be collected and disposed accordingly. The container should be air-dried, deface the label & mark as "EMPTY". Glass container should be disposed of in a broken glass receptacle if chemical is not hazardous. If the empty container is metal or plastic and the chemical is not on the Acutely Hazardous Waste list, it should be disposed of in the regular trash.

If possible, empty chemical containers may be reused to hold non-hazardous waste, if they have been properly cleaned and decontaminated.

If the chemical is identified as Acutely Hazardous Wastes, fill the container to approximately 10% full with water or suitable solvent. Replace the lid, then vigorously shake and swirl the container so that all parts of the inside of the container are thoroughly rinsed. Pour out the rinsate from the container into a properly labeled hazardous waste container for disposal. Repeat above steps for another 2 times. Once the container has been rinsed a total of 3 times, remove or deface the label, and mark as "EMPTY". The container is now ready to be disposed of in the regular trash.

2.6 Disposal of gloves, mask

Non-contaminated gloves should be discarded in a designated waste receptacle, typically a lined trash bin. If the gloves are contaminated with hazardous materials, they should be disposed of as hazardous waste, following specific protocols.

Used mask waste must be incinerated or disposed in landfills without recycling.

2.7 Disposal of Vials & ampoules

Empty vials & ampoules should be crushed on hard, impermeable surface or within a metal container using a heavy object and should be collected, placed in a puncture-resistant container, sealed & then disposed in landfill. Any volatile substances in ampoules can be evaporated outdoors but non-volatile liquids should be diluted before disposal. Ampoules containing anticancer or anti-infective drugs should be encapsulated or intertized during disposal.

2.8 Disposal of Contaminated micropipette tips, contaminated media, expired growth media

Contaminated micropipette tips can be submerged in disinfectant solution followed by autoclaving.

Contaminated media should be decontaminated first by autoclaving at 121°C for 60 minutes or can also be treated with chemicals like bleach or disinfectant. After which media can often be disposed of through normal waste disposal or incineration procedures.

Expired growth media should be autoclaved first & then disposed of through normal waste disposal methods or incineration.

2.9 Disposal of Chemically contaminated waste water

Treatment process like neutralization, oxidation/reduction, and precipitation can be done to convert harmful chemicals into less toxic form. Discharging of liquid waste into slow moving or stagnant bodies of water can risk aquatic life & water quality.

2.10 Disposal of Corrugated box, duplex, papers

These materials can be recycled, burnt (if not feasible to recycle) or landfilled (if neither recycling nor burning is practical).

3. Summary

Waste Management Hierarchy which prioritizes waste prevention & reduction followed by reuse, recycling, treatment & disposal should be followed as source reduction or pollution prevention is the most effective means of minimizing the environmental and health impacts of hazardous chemical waste which includes reducing or eliminating the use of hazardous chemicals and thereby decreasing the amount of waste generated. For waste that is generated, the preferred management methods are recycling, followed by combustion for energy recovery, treatment, and, as a last resort, safe disposal or release of chemical waste into the environment. Adhering to

this hierarchy during laboratory waste handling not only ensures compliance with regulatory standards but also supports a safe and sustainable approach to waste management. Promoting awareness, proper training, and the implementation of suitable disposal techniques are essential for protecting public health and the environment.

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Ensuring Drug Safety: Enhancing competence of Drug Testing Laboratories

Sadhana Dahal- Pharmacy Officer

Introduction

In the realm of healthcare, medicine wields an immense power to diagnose, treat, and prevent ailments. Its influence on human well-being spans pain management, early disease detection, mental health support, and disease outbreak control. The relentless march of global drug innovations across centuries has significantly elevated life expectancy, underscoring medicine's paramount role in enhancing human existence. Many diseases that were once fatal are now manageable or preventable, leading to longer and healthier lives for many individuals. Medicine thus has a great impact on overall well-being. So far, a wave of global drug and chemical innovations has continuously increased life expectancy by 2.5 years per decade from 1840 to 2002 (Boudoulas, KD 2017). Behind the scenes of every effective pharmaceutical, however, stand the watchful protectors - drug testing laboratories. This article embarks on an exploration of the hurdles encountered by Nepalese drug testing laboratories and unveils strategic pathways for augmenting their prowess. This journey is aimed at fortifying the safety and quality of medicines, contributing to the betterment of the nation's health.

Drug Safety & Drug laboratories

Drug safety has earned a lot of attention in daily medical practice and is given a greater priority due to its major role in patients' health. With regard to approving new medication or questioning the possibility of withdrawing a drug from the market, a comprehensive concept of drug safety is significant. It is really hard to figure out the loss that people and the country have to bear with counterfeit and substandard drugs. That is where the importance of a good drug laboratory comes into play. It is through a good laboratory that the safety and quality of the drug are ensured. Drug testing laboratories analyze and evaluate the safety, efficacy, and potential risks associated with pharmaceuticals. While assuring quality, laboratories ensure that the composition, purity, and strength of active ingredients do meet quality standards. Quality personnel involved confirm the absence of impurities through various tests so that health risks related to medicine are minimized. Every pharmaceutical product that reaches the market is pre-analyzed in the quality control laboratory

of the pharmaceutical industry.

Nevertheless, laboratories continue to monitor the quality and safety of pharmaceutical products even after they are released to market so that any deviations from quality standards can be detected and rectified. It is always essential to regularly monitor such labs, which have a direct effect on the public's health, by regulatory bodies. Continuous or regular monitoring is considered vital for reproducibility, integrity, and quality control. Regulatory oversight will help ensure accountability and maintain the integrity of the drug testing process in the pharmaceutical industry.

But again, the one who has the authority to monitor, i.e., the laboratory of the regulatory body of the government, must be strong enough to reproduce accurate data. It is through these data and test results that come from the laboratory that can make informed decisions about the safety and quality of drugs, which are directly related to public health. In Nepal, the only drug testing laboratory under the government is the National Medicinal Laboratory (NML), which is responsible for quality control and regulation of medicines and pharmaceutical products in the country. It has the primary role of testing, analyzing, and ensuring the quality, efficacy, and safety of medicines in the Nepalese market.

Current Landscape of Drug Testing Laboratories in Nepal

Central to Nepal's healthcare landscape, the National Medicinal Laboratory (NML) shoulders the responsibility of ensuring the quality and regulation of medicines and pharmaceuticals. Yet, the panorama of drug laboratories in Nepal is marred by a slew of challenges impeding their optimal functionality. This section sheds light on the precise challenges and gaps confronting Nepalese drug testing laboratories.

Challenges and Gaps in Nepalese Drug Testing Laboratories

1. **Outdated Regulations and the Call for Reevaluation** Nepal's burgeoning pharmaceutical sector, boasting over 128 private allopathic drug entities, operates in the shadow of outdated and inadequate regulations. The absence of revised regulations forms a significant hurdle in guaranteeing the quality and safety of medicines within the market.

2. **Inadequate Infrastructure and Resource Constraints** Laboratories, ill-equipped and constrained by limited resources, grapple with the challenge of conducting accurate and dependable tests. Scarce budgets further hinder the procurement of advanced equipment, upkeep of essential facilities, and training for staff members.

3. **Feeble Data Management and Environmental Concerns** Laboratories wrestle with subpar data management practices, resulting in potential inaccuracies and the incapacity to maintain accurate records. Additionally,

the dearth of guidelines for pharmaceutical waste disposal harbors the potential for environmental pollution and public health hazards.

Strategies for Enhancing Drug Testing Laboratories in Nepal

Navigating these challenges necessitates a multi-faceted approach for rejuvenating drug testing laboratories in Nepal. This segment outlines a comprehensive set of strategies, poised to elevate the overall efficacy and impact of these indispensable institutions.

1. **Regulatory Reforms and Augmented Financial Backing** Overhauling regulations stands imperative to harmonize practices with contemporary pharmaceutical trends. Adequate financial support enabling the upgrade of infrastructure, acquisition of cutting-edge equipment, and the execution of requisite training programs.

2. **Collaboration among Regulatory Agencies, Industry, Academia, and International Entities** Forging alliances and knowledge exchange among key stakeholders fosters the dissemination of best practices, insights, and resources. Collaborative endeavors usher in a holistic approach to bolstering drug testing laboratories.

3. **Nurturing Personnel and Leadership via Capacity-Building Programs** Continuous training and skill development programs for lab staff act as strong defenses against becoming outdated. Teaching leadership skills to management teams also greatly enhances overall efficiency and effectiveness.

4. **Instituting a Digital Data Management System** A digital data management system serves to refine record-keeping and enhance access to vital information, promoting precision and traceability within drug testing processes.

5. **Training for Equipment Maintenance and Troubleshooting** Equipping staff with troubleshooting expertise and the know-how for routine equipment maintenance extends machinery longevity, diminishes repair expenses, and minimizes operational interruptions.

6. **Advocating Green Practices and Prudent Pharmaceutical Waste Management** Framing guidelines for pharmaceutical waste disposal and fostering eco-conscious practices safeguards both the environment and public health, in alignment with global sustainability aspirations.

Success Stories from Around the Globe: Catalysts for Nepal's Ascent

There are several countries that have made significant improvements in their drug laboratories. Historically, like Nepal, the Medicines Control Authority of Zimbabwe (MCAZ), the Central Drugs Standard Control Organization **(**CDSCO) of India (MCAZ), and

many laboratories in south-east Asia faced challenges related to regulatory inefficiency, inadequate resources, a lack of transparency, delay in drug approval, and many others. Now MCAZ is an ISO/IEC 17025-accredited and WHO-prequalified laboratory, which is the Regional Centre of Regulatory Excellence (RCoRE) of the New Partnership for Africa's Development (NEPAD). WHO prequalification combined with ISO 17025 accreditation has placed its chemistry laboratory in a strategic position to contribute its best in local and global level by providing excellent medicine quality control services.(Sithot.T et.al 2021)

Likewise, the reforms taken by CDSCO are exemplary (George, B. 2017).We can see the Indian pharmaceutical market expanding rapidly, and has been involved in vaccine production and many other biotechnological and pharmaceutical products. The reforms undertaken by CDSCO, MCAZ, and many others are examples behind us that the drug testing laboratory can address its shortcomings and transform into a more effective and responsive body, thereby ensuring the safety and quality of medicines.

Conclusion: Paving the Path to a Healthier Future

Nepal's voyage towards a healthier populace underscores the urgency of transforming drug testing laboratories. Sourced from tales of global achievement, these laboratories can transcend their present limitations. Regulatory reforms, harmonized stakeholder cooperation, inventive capacity-enhancement schemes, and reimagined waste management methodologies collectively possess the potential to revolutionize Nepal's drug testing arena. However, the journey demands a concerted orchestra of government, industry, academia, and international cohorts. By embracing transformation, aligning with universal benchmarks, and unflinchingly prioritizing safety, Nepal's drug testing laboratories can etch their legacy as sentinels of public health, ushering in a brighter and healthier future for all.

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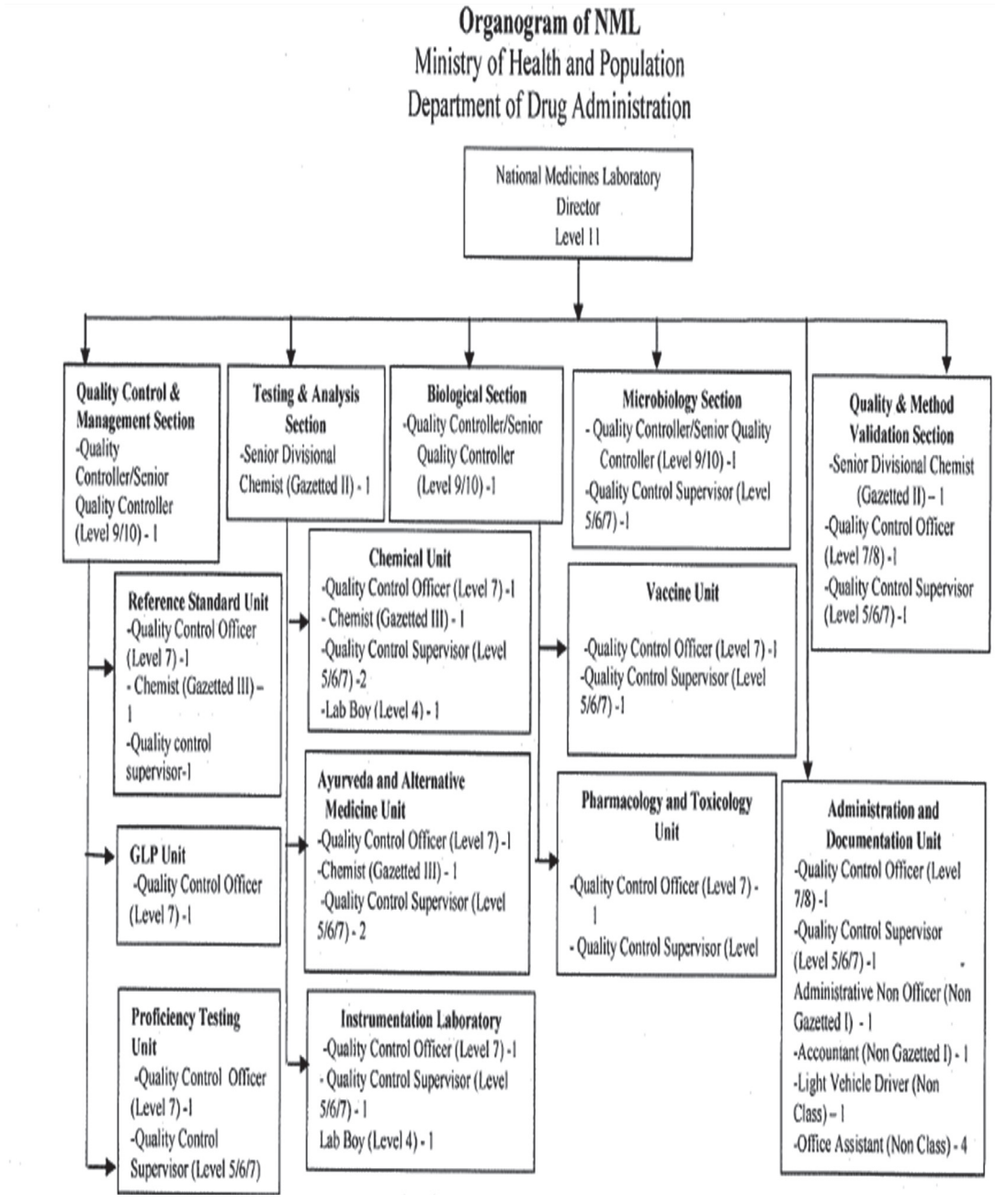
Section III
ANNEXES

ANNEX-1


Organogram of NML
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Director
Level 11
Quality Control & Management Section
-Quality Controller/Senior Quality Controller (Level 9/10) - 1
Testing & Analysis Section
-Senior Divisional Chemist (Gazetted II) - 1
Biological Section
-Quality Controller/Senior Quality Controller (Level 9/10) -1
Microbiology Section
- Quality Controller/Senior Quality Controller (Level 9/10) -1
-Quality Control Supervisor (Level 5/6/7) -1
Quality & Method Validation Section
-Senior Divisional Chemist (Gazetted II) – 1
-Quality Control Officer (Level 7/8) -1
-Quality Control Supervisor (Level 5/6/7) -1
Reference Standard Unit
-Quality Control Officer (Level 7) -1
- Chemist (Gazetted III) – 1
-Quality control supervisor-1
Chemical Unit
-Quality Control Officer (Level 7) -1
- Chemist (Gazetted III) - 1
-Quality Control Supervisor (Level 5/6/7) -2
-Lab Boy (Level 4) - 1
Vaccine Unit
-Quality Control Officer (Level 7) -1
-Quality Control Supervisor (Level 5/6/7) -1
GLP Unit
-Quality Control Officer (Level 7) -1
Ayurveda and Alternative Medicine Unit
-Quality Control Officer (Level 7) -1
-Chemist (Gazetted III) - 1
-Quality Control Supervisor (Level 5/6/7) - 2
Pharmacology and Toxicology Unit
-Quality Control Officer (Level 7) - 1
- Quality Control Supervisor (Level
Administration and Documentation Unit
-Quality Control Officer (Level 7/8) -1
-Quality Control Supervisor (Level 5/6/7) -1
Administrative Non Officer (Non Gazetted I) - 1
-Accountant (Non Gazetted I) - 1
-Light Vehicle Driver (Non Class) – 1
-Office Assistant (Non Class) - 4
Proficiency Testing Unit
-Quality Control Officer (Level 7) -1
-Quality Control Supervisor (Level 5/6/7)
Instrumentation Laboratory
-Quality Control Officer (Level 7) -1
- Quality Control Supervisor (Level 5/6/7) - 1
Lab Boy (Level 4) - 1

ANNEX-2

Citizen charter

नेपाल सरकार
स्वस्थ्य मन्त्रालय
औषधि व्यवस्था विभाग
राष्ट्रिय औषधि प्रयोगशाला

नागरिक वडापत्र

उद्देश्य	सेवाको प्रकार	कार्य प्रकृती	सेवाग्राही समूह	सेवा उपलब्ध हुने प्रकृया	सेवा वापत लाग्ने दस्तुर	पेश गर्नुपर्ने कागजाहरु	आवश्यक नमुनाको परिमाण	समय	जिम्मेवार अधिकारी	निर्णय गर्ने अधिकारी	कैफियत
औषधि ऐनको दफा ६ (१) मा व्यवस्था भए अनुसार औषधिको वैज्ञानिक अनुसन्धान परिक्षण र विश्लेषण गर्ने।	विभिन्न किसिमका औषधि तथा सो मा प्रयोग हुने कच्चा पदार्थहरु को रासायनिक, जैविक, उपकरणिय, भौतिक परिक्षण तथा विश्लेषण कार्य गर्ने ।	विभिन्न प्रकृतीका औषधिहरु जस्तो Tablet, Capsule, Liquid Ointment Injection आदीको फर्माकोपिया तथा अन्य अधिकारीक विश्लेषण विधि अपनाई विश्लेषण कार्य गर्ने ।	सरकारी निकायहरु तथा विभिन्न संघ संस्था, औषधि उत्पादक कर्ता, पैठारी कर्ता ।	सेवाग्राहीले विश्लेषण गर्नुपर्ने औषधिको उद्देश्य खुलाई आवश्यक औषधिको परिमाण तथा कागजातहरु संकलन गरि केन्द्रिय नमुना व्यवस्था शाखामा आवश्यक प्रकृया को लागि पेश गर्ने ।	केन्द्रिय नमुना व्यवस्था शाखाको प्रकृया पुरा भएपछि अनुसुचिमा उल्लेख भए बमोजिमको दस्तुर लेखा शाखामा बुझाउने ।	आवेदन फाराम १: नमुनाको विवरण (परिक्षण आवेदनको क्र.सं.....सग सम्बन्धित नमुनाको विवरण) १ परीचय: १.१ नमुनाको नाम: १.५ ब्याच।लट नं १.२ ब्रान्ड १.६ उत्पादन मिति: १.३ प्याक साईज १.७ मुल्य मिति: १.४ प्रेशित परिमाण १.८ समुह: १.९ उत्पादकको नाम: २ परीक्षण गरिनुपर्ने गुण/तत्व (Testing Parameter) २.१ ब्रान्डको परिचय (Dosage Form): २.२ पहिचान (Identification): तोक्नुपरेमा २.३ परख (Assay): २.४ दुषण तत्व (Impurities): तोक्नुपरेमा २.५ अन्य (तोक्नु पर्ने): (i) Disintegration/Dissolution (ii) Content Uniformity (iii) etc. ३ नमुनाको साथमा पेश गर्नुपर्ने कागजातहरु ३.१ उत्पादन अनुज्ञाप्त (Manufacturing License) छ/छैन ३.२ औषधिको विवरण (Product Specification) छ/छैन ३.३ औषधिको गुणस्तर विरण (Quality Control Spacification) छ/छैन ३.४ परीक्षण विधि (पुर्ण) (Method of Analysis) छ/छैन ३.५ परिक्षण प्रतिवेदन (उद्योगको प्रयोगशालामा) (Certificate of Analysis) छ/छैन (i) Raw Data with Spectrum/Chromatogram/TLC Plate (Photograph छ/छैन (ii) Calculation छ/छैन (iii) Reference Standard छ/छैन ३.६ Stability Report छ/छैन ४ निवेदक/सरोकारवाला व्यक्तिको नाम: (Technical Person Name): दर्जा (Designation) : Contact Details: हस्ताक्षर(Signature) : छाप (Stamp) :	Quantities of samples required 1. No. of Tablet a. Tablets≤80 mg (Uncoated) 200 Tablets b. Tablets≤80 mg (Coated) 150 Tablets c. Tablets≤350 mg (Coated & Uncoated) 150 Tab. d. Tablets>350 mg (Coated & Uncoated) 100 Tab. 2. No. of Capsule 100 Capsules 3 Liquid a. ≤30 ml 20 Bottle b. >30 ml 15 Bottle 4. Powder (Oral and External) 25 Pkt. 5. Injection/Solution/Suspension: a. Less than 10 ml vials. 60 b. 10 ml or less than 100 ml vias. 40 c. 100 ml or more vial/bottle 30	औषधिको विश्लेषण गरिने नमुनाहरुको प्रकृती अनुसार साधारणतया ३ महिना समय लाग्न सक्ने छ ।	निर्देशक ज्यू	निर्देशक ज्यू	विभिन्न नमुना विश्लेषणका लागि जानजात र परिमाण फरक पर्न सक्ने भएकाले सम्बन्धित नमुनाको लागि आवश्यक जानकारी सम्पर्क अधिकारी वा केन्द्रिय नमुना व्यवस्था शाखाबाट लिन सकिने छ।

Annex-3

Minimum Quantities of Samples required for analysis

S.N.	Dosage form	Test Parameter	Quantities Required			
			Initial Test	Repeat Test 1	Repeat Test 2	Control Sample
	Tablets	Assay +Identification+ Weight Variation	20	20		100
		Dissolution	6	6	12	
		Uniformity of Content	10	20		
		Friability (For uncoated and average weight greater or equal to 0.65 g)	10			
		Friability (For uncoated and average weight less than 0.65 g)	More than 10-tab weighing 6.5 g			
		Disintegration	6	6		
	Capsules	Assay + Identification+Weight Variation	20	20		50
		Dissolution	6	6	12	
		Uniformity of Content	10	20		
		Disintegration	6	6		
	Liquid Oral	Identification+Assay	**2**	**2**		5
		Fill volume variation	10	10		
	Powder for Oral Liquid	Identification+Assay	**3**	**3**		5
		Fill volume variation	10	10		

S.N.	Dosage form	Test Parameter	Quantities Required			
			Initial Test	Repeat Test 1	Repeat Test 2	Control Sample
	Sterile Liquid for Injection	Identification+Assay	**3**	**3**		Large volume =20 Small Volume=30
		Fill volume variation	10	10		
		Uniformity of content	10	30		
		Sterility test (for large volume > 100 ml	10	10		
		Sterility test (for small volume ≤ 100 ml	20	20		
		Bacterial Endotoxin (if required)	**5**	**5**		
	Sterile Powder for Injection	Identification+Assay	**3**	**3**		Large volume =20 Small Volume=30
		Fill volume variation	20	20		
		Uniformity of content	10	30		
		Sterility test (for large volume > 100 ml	10	10		
		Sterility test (for small volume ≤ 100 ml	10	10		
		Bacterial Endotoxin (if required)	**5**	**5**		
	Eye/Ear Drop/ Sterile Ointment	Identification+ Assay	**3**	**3**		15
		Fill weight variation	10	10		
		Sterility	10	10		
		Microbiological Assay if required	2 tubes per API	2 tubes per API		
	Ointment/ Cream	Identification+Assay	**3**	**3**		5
		Fill weight variation	10	10		
		Microbiological Assay if required	2 tubes per API	2 tubes per API		
	Herbal Powder/ Liquid/ Paste	Identification+Assay	3	3		1
		Fill volume/Fill weight variation	10	10		
		Microbiology	3	3		

ANNEX-4

२. राष्ट्रिय औषधि प्रयोगशाला तर्फ

प्रस्तावित विश्लेषणको दररेट

विश्लेषणका प्रकार		बर्तमान दर	प्रस्तावित दर
1. Biological test of Drugs requiring use of animals			
(i)	Pyrogen Test, Safety test, Toxicity test etc.	700/-	3,000/-
2. Microbiological tests and assays			
(I)	Bacterial Endotoxin Test		5,000/-
(ii)	Bioassay of Antibiotic (Each)	800/-	1,500/-
(iii)	Microbiological assay of vitamins(Each)	800/-	1,500/-
(iv)	Sterility Test	600/-	3,000/- (Additional 1000)
3. Microbial Enumeration Test			
(i)	Total bacterial count	600/-	1,000/-
(ii)	Fungal count	600/-	1,000/-
4. Tests for specified microorganism			
(i)	For each organism	300/-	2,000/-
5. Vaccine Document study for lot release		1,800/-	2,000/-
6. Test for particulate matter			2,000/-
7. Physiochemical tests			
Identification tests			
Chemical Methods:			
(i)	Thin layer Chromatography	250/-	400/-
Instrumental:			
(i)	Microscopical	250/-	400/-
(ii)	Refractive Index	250/-	400/-
(iii)	Optical rotation		400/-
(iv)	UV Spectrophotometer	250/-	400/-
(v)	Gas Liquid Chromatography (GLC)	250/-	1,000/-
(vi)	High Performance Liquid Chromatography (HPLC)	250/-	1,000/-
(vii)	Atomic Absorption Spectroscopy (AAS) per metal		500/-
(viii)	Flame photometer per metal		500/-
(ix)	Spectrofluorometer		500/-
(x)	Infrared Spectroscopy (IR)		500/-
Uniformity of weight			
(i)	Tablets	50/-	100/-
(ii)	Capsules	100/-	150/-
(iii)	Sachets	150/-	150/-
(iv)	Creams/Ointments	200/-	200/-
Uniformity of Volume			200/-
Specific Gravity/Weight per ml			
(i)	With distillation		600/-
(ii)	Without distillation	250/-	400/-
Sulphated ash			500/-
pH			100/-
Acid Neutralizing capacity			400/-
Karl Fischer Titration (Water determination)			500/-
Loss on Drying			300/-
Friability			100/-
Hardness Test			100/-
Leak test			200/-
Nitrogen Determination			1,000/-
Acid value, Iodine value, peroxide value, Saponification value, acetyl value (Each)			1,000/-

Disintegration test		
(i) Tablets	250	400
(ii) Capsules	250	400
(iii) Enteric coated Tablets	100/-	600/-
8. Dissolution test		
(i) UV Spectrophotometer	400/- Each additional API 200/-	1,200/- each
(ii) HPLC	400/- Each additional API 200/-	5,000/- Each additional API 1,000/-
(iii) Titration	400/- Each additional API 200/-	1,000/- Each additional API 500/-
9. Uniformity of content		
(i) UV spectrophotometer	1,400/-	4,000/-
(ii) HPLC	1,400/-	8,000/-
(iii) Titration	1,400/-	3,000/-
10. Impurities		
(i) Limit tests for impurities (chemical)		300/-
11. Related substances & Impurities		
TLC method		
(i) Without using reference standard		500/-
(ii) Using reference standard		1,000/-
Gas Liquid Chromatography (GLC)		
(i) Without using reference standard(Each Item)	800/-	2500/-
(ii) Using reference standard(Each Item)	800/-	3500/-
High Performance Liquid Chromatography (HPLC)		
(i) Without using reference standard(Each Item)	800/-	2500/-
(ii) Using reference standard(Each Item)	800/-	5000/-
12. Assay		
Chemical		
(i) Titration(Each Item)		1000/-
Instrumental		
(i) UV Spectroscopy(Each Item)	400/-	1,000/-
(ii) GLC (Each Item)	800/-	2,500/-
(iii) HPLC	800/-	2,500/- (Each additional API 1,000/-)
(iv) AAS		
a. Flame technique per metal		1,500/-
b. Graphite technique per metal		2,000/-
c. Hydride Vapour Generator (HVG) Technique per metal		2,000/-
(v) Flame Photometer per metal		1,000/-
(vi) Spectrofluorimeter (Each Item)		1,000/-
(vii) Optical rotation		1,000/-
13. NML visit20 person/class		1,000/-
14. B. Pharm Student training/day		1,000/-
15. GLP certification charge/year		7,500/-
16. GLP certificate charge		500/-

निशुल्क विश्लेषण सम्बन्धमा:

क) निरीक्षण र अनुसन्धानका क्रममा औषधि व्यवस्था बिभागबाट पठाइएका औषधिहरु ।

ख) अदालतबाट पठाइएका तथा नेपाल सरकारले निःशुल्क परिक्षण गर्ने भनी तोकिएका औषधिका नमुनाहरु ।

ग) राष्ट्रिय औषधि प्रयोगशालाको संस्थागत बिकासको लागि अन्य स्वदेशी तथा बिदेसी संघ संस्थासंग प्राबिधिक सहयोग तथा दक्षता आदानप्रदान गर्ने सिलसिलामा हुने विश्लेषण कार्य ।

ANNEX-5

List of AMV profile

S.N	Product Name	Analytical Profile No.	Remarks
1	Amlodipine & Telmisartan Tablet	AmloTelmi 073/074/AP 001	Monograph Available in IP 2018
2	Diacerin Tablet	As per IP monograph of Diacerin Capsule (latest edition)	
3	Rabeprazole Capsule	As per IP monograph Rabeprazole Gastro resistant Tablets (latest edition)	Monograph Available in USP 2021
4	Desloratidine tablet	Delor 073/074/AP 004	Monograph Available in USP 2024
5	Esomeprazole Capsule	As per IP monograph of Esomeprazole Tablet (latest edition)	Monograph Available in IP 2018
6	Amlodipine & Atorvastatin Tablets	Amlo Telmi 073/074/AP006	Monograph Available in USP 2024
7	Cefdinir dispersible Tablets	Cefdi 073/074/AP 007	
8	Levocetirizine syrup	Levc 073/074/AP 008	
9	Fexofenadine suspension	Fex 073/074/AP 009	
10	Sofosbuvir Tablet	Sof 073/074/AP 010	Monograph available in IP 2022
11	Ibuprofen & Paracetamol Suspension	Ibu ParS 073/074/AP 011	
12	Linagliptin Tablets	Lina 073/074/ AP 012	
13	Metronidazole & Diloxanide Furoate Tablets	Metr Dilo 073/074/ AP 013	
14	Amiloride+Frusemide Tablet	Ami Fru 073/074/AP 014	Monograph available in BP 2017 & IP 2018 Addendum 2019
15	Metformin + Glimepiride Tablet	Met Gli 073/074/ AP 015	Monograph available in IP 2018
16	Metformin + Sitagliptin Tablet	Met Sit 073/074/ AP 016	
17	Febuxostat Tablet	Febu 073/074/AP 017	
18	Ibu par	Ibu Para T 074/075/ AP 018	Monograph available in IP 2018
19	Liquid Antacids	ATO S 074/075/AP 019	

S.N	Product Name	Analytical Profile No.	Remarks
20	Tapentadol Capsules	Tap 074/075/AP 020	
21	Metformin (Immediate release) + Sitagliptin Tablet	MetI Sit 073/074/ AP 021	
22	Folic acid & Ferrous Ascorbate Tablets	FFT 074/075/AP 022	
23	Pantoprazole powder for injection	PPI 074/075/ AP 023	Monograph available in BP 2018 & IP 2022 Addendum 2024
24	Itopride HCl tablet	ITO 074/075/ AP 024	
25	Chlorzoxazone & Paracetamol tablets	Chl Para 074/075/ AP 025 *Replaced by Chl Para 075/076/AP 025	
26	Rifaximin Tablet	RIF 074/075/AP 026	Monograph available in IP 2022 Addendum 2024
27	Illaprazole Tablet	ILL 074/075/AP 027	
28	Silodosin Capsule	SIL 074/075/AP 028	
29	Linagliptin & Metformin sustained release tablet	LMS 074/075/AP 029	
30	Linagliptin & Metformin immediate release tablet	LMI 074/075/AP 030	
31	Sodium Valproate + Valproic acid Tablet	SVT 074/075/AP 031	
32	Aceclofenac sustained release tablet	AST 074/075/AP 032	
33	Itopride HCl sustained release tablet	ISR 074/075/AP 033	
34	Cefpodoxime + Clavulanic acid Powder for oral suspension	CCP 074/075/AP 034	
35	Disodium hydrogen citrate syrup	DCS 075/076/AP 035	
36	Dutasteride Tablet	DUT 075/076/AP 036	
37	Dabigatran Etexilate Mesylate Capsule	DAB 075/076/AP 037	
38	Tropicamide & Phenylephrine HCl eye drops	Trop Phen 075/076/AP 038	

S.N	Product Name	Analytical Profile No.	Remarks
39	S – Pantoprazole enteric coated tablet	S(-)PAN 075/076/AP 039	
40	Daclatasvir Dihydrochloride Tablet	DAC 075/076/AP 040	
41	Clobazam mouth dissolving tablet	CLOB 075/076/AP 041	
42	Sofosbuvir & Ledipasvir tablet	SOF LED 075/076/AP 042	
43	Cefoperazone & Sulbactam injection	CEF SUL 075/076/AP 043	
44	Empaglifozin Tablet	EMPA 075/076/AP 044	
45	Deflazacort Tablet	DEFLA 075/076/AP 045	
46	Ornidazole Tablet	ORNI 075/076/AP 046	
47	Sevelamer Carbonate Tablet	SEVL 075/076/AP 047	
48	Cefpodoxime Proxetil Dispersible Tablet	CEFPO 075/076/AP 048	
49	Dextromethorphan HBr, Triprolidine HCl & Phenylephrine HCl Tablet	Dex Tri Phen 075/076/AP 049	
50	Calcium Polystyrene Sulphonate Oral Powder	Calp 075/076/AP 050	
51	Nimesulide Tablet	NIMES 075/076/AP 051	
52	Terbutaline Sulphate & Bromhexine HCl syrup	BROM TERB 075/076/AP 052	
53	Telmisartan & Chlorthalidone Tablets	Telmi Chlor 075/076/AP 053	
54	Ibandronate Sodium Tablets	Iban 075/076/AP 054	
55	Potassium Iodide, Sodium Chloride & Calcium Chloride ophthalmic solution	PSCO 075/076/AP 055	
56	Tapentadol Tablet	Tap T 075/076/AP 056	
57	Granisetron MD Tablet	Grani 075/076/AP 058	
58	Granisetron Syrup	Grani 075/076/AP 059	

S.N	Product Name	Analytical Profile No.	Remarks
59	Teneligliptin Tablet	Teneli 075/076/AP 060	Monograph available in IP 2018 Addendum 2019
60	Sucralfate Suspension	Sucral 076/077/AP 057	
61	Esomeprazole Fast Releasing Tablet	Esmo FR 076/077/AP 061	
62	Iron Polymaltose Complex & Folic acid capsule	IPFC 076/077/AP 062	
63	Amlodipine & Ramipril Tablet	Amlo Rami 076/077/AP 063	
64	Salbutamol Sulphate & Bromhexine HCl Syrup	Salb Brom 076/077/AP 064	
65	Sodium Picosulphate Tablets	Sodp 076/077/AP 065	
66	Linezolid & Dextrose Injection	Linez 076/077/AP 066	
67	Enrofloxacin Oral Solution (Veterinary)	Enrof 076/077/AP 067	
68	Moxifloxacin Eye Ointment	Moxif 076/077/AP 068	
69	Metronidazole & Diloxanide Furoate Suspension	Metr Dilo L 076/077/AP069	
70	Progesterone SR Tablet	Prog SR 076/077/AP070	
71	Esomeprazole Sodium for Injection	Esmo I 076/077/AP 071	
72	Ambroxol Hydrochloride Syrup	Ambrx 076/077/AP 073	
73	Cefpodoxime Proxetil & Potassium Clavulanate Tablet	Cefpo clav 076/077/AP 074	
74	Cefpodoxime Proxetil & Potassium Clavulanate Dispersible Tablet	Cefpo clav DT 076/077/AP 075	
75	Folic acid & Ferrous Ascorbate Capsules	FFC 076/077/AP 076	
76	S(-) Amlodipine & Hydrochlorothiazide Tablets	Amlo Hydro 076/77/AP 076	
77	Rivaroxaban Tablet	Riva 076/077/AP 077	Monograph Available in USP 2024
78	Metronidazole & Furazolidone bolus (vet)	Metr Fur 076/077/AP 078	

S.N	Product Name	Analytical Profile No.	Remarks
79	Norfloxacin oral powder (vet)	Norf 076/077/ AP 079	
80	Solifenacin Succinate Tablets	Solf 076/077/ AP 080	
81	Levofloxacin oral soln (vet)	Levo V 077/078/AP 081	
82	Favipiravir Tablet	Favi 077/078/AP 083	
83	Dextromethorphan HBr, chlorpheniramine Maleate & Phenylephrine HCl syrup	Dex Chlor Phen 077/078/AP 085	
84	Ivabradin Tablet	Ivab 077/078/AP 086	
85	Bromhexine HCl, chlorpheniramine Maleate & Phenylephrine HCl syrup	Brom Chlor Phen 077/078/AP 087	
86	Ticaglelor Tablet	Tica 077/078/AP 088	
87	Florfenicol Oral Solution (Vet)	Flor 077/078/AP 089	
88	Flunarizine Tablets	Fluna 077/078/AP 090	
89	Levetiracetam Dispersible Tablet	Leveti 077/078/AP 091	
90	Cefixime & Potassium Clavulanate Tablets	Cefi Potas 077/078/AP 092	
91	Amlodipine Besylate & Hydrochlorothiazide Tablet	Amlo Hychlo 077/078/AP 093	
92	Ambroxol HCl Drops	Ambrx D 077/078/AP 094	
93	Mefenamic Acid Oral Suspension	Mefe 077/078/AP 095	Monograph available in IP 2022 Addendum 2024
94	Cefdinir Tablets	Cefdi T 077/078/AP 096	
95	Brimonidine Tartrate & Timilol Maleate eye drops	Brim Timil 078/079/AP 097	
96	Frusemide & Spironolactone Tablet	Fru Spiro 078/079/AP 098	
97	Dextromethorphan HBr, Triprolodine HCl & Phenylephrine HCl syrup	Dex Tri Phen S 078/079/AP 099	
98	Clomipramine HCl Tablets	Clomi 078/079/AP 100	
99	Levodropropionate & Chlorpheniramine Maleate Syrup	Levo Chlor 078/079/AP 101	

S.N	Product Name	Analytical Profile No.	Remarks
100	Cholecalciferol Drops	Chole D 078/079/AP 102	
101	Tramadol HCl Injection	Trama 078/079/AP 104	
102	Cholecalciferol chewable Tablet	Chole 078/079/AP 105	
103	Dexlansoprazole delayed release Capsules	Dexlans 078/079/AP 106	
104	Desvenlafaxine Extended Release Tablets	Desven 078/079/AP 108	
105	Montelukast Sodium & Levocetrizine Dihydrochloride Syrup	Monte Levocet 078/079/AP 109	
106	Levosalbutamol Syrup	Levosal 078/079/AP 110	
107	Montelukast Sodium & Levocetrizine Hydrochloride Dispersible Tablets	Monte Levocet DT 078/079/AP 112	
108	Drotaverine HCl Injection	Drotav 078/079/AP 113	
109	Rofumilast Tablet	Rofumi 078/079/AP 114	
110	Rocumide Injection	Rocu 078/079/AP 115	
111	Estradiol Valerate Tablet	Estra 079/080/AP 116	
112	Cholecalciferol Soft gel Capsules	Chole C 079/080/AP 117	
113	Diclofenac Sodium Suppository	Diclo 079/080/AP 118	
114	Paracetamol, Chlorpheniramine Maleate & Phenylephrine HCl Syrup	Para Chlor Phen 079/080/AP 119	
115	Dextromethorphan HBr & Chlorpheniramine Maleate Syrup	Dex Chlor 079/080/AP 120	
116	Ketorolac Tromethamine eye drops	Keto 079/080/AP 103	
117	Oxetacain & Sucralfate Suspension	Oxe Sucral 079/080/AP 121	
118	Memantine HCl & Donepezil HCl Tablets	Meman Donep 079/080/AP 122	
119	Tranexamic Acid Capsules	Tranex 079/080/AP 123	
120	Moxifloxacin HCl Infusion	Moxiflo 079/080/AP 124	

S.N	Product Name	Analytical Profile No.	Remarks
121	Levosalbutamol & Beclomethasone Dipropionate powder for Inhalation	Levosal Beclo 079/080/AP 107	
122	Levosalbutamol Inhalation Solution	Levosal I 079/080/AP 125	Monograph available in IP 2022
123	Glycopyrronium powder for inhalation	Glycopy 079/080/AP 126	
124	Oxyclozanide & Levamisole Suspension (Vet)	Oxyclo Levami 079/080/AP 127	
125	Dienogest Tablets	Dieno 079/080/AP 128	
126	Metamizole Sodium Injection	Metami 079/080/AP 129	
127	Dapagliflozin Tablets	Dapa 079/080/AP 130	
128	Levamisol HCl oral powder (vet)	Levami 079/080/AP 131	
129	Bromhexine HCl oral solution (vet)	Brom 079/080/AP 132	
130	Tiamulin Hydrogen Fumarate Oral Powder(Vet)	Tiamu 079/080/AP 133	
131	Carboxymethylcellulose Eye drops	Carboxy 080/81/AP 134	Monograph available in IP 2022
132	Apixaban Tablets	Apixa 080/81/AP 135	
133	Azelastine HCl and Fluticasone Propionate Nasal Spray	Aze Fluti 080/81/AP 136	
134	Diaveridine and Sulphaquinoxaline Powder(Vet)	Diave Sulpha 080/81/AP 137	
135	Piperazin Hydrate oral solution (VET)	Pipera 080/81/AP 138	
136	Cefixime and Clavulanic Acid Oral Suspension	Cefix Calvu 080/81/AP 139	
137	Solution of Glycerin and Sodium Chloride	Gly Sod 080/81/AP 140	
138	Levodropropizine Syrup	Levodro 080/81/AP 141	
139	Enrofloxacin Tablets (Veterinary)	Enro 080/81/AP 142	
140	Sacubitril and Valsartan Tablets (50MG)	Sacub Val 080/81/AP 143	

S.N	Product Name	Analytical Profile No.	Remarks
141	Paracetamol, Phenylephrine HCl,Chlorpheniramine Maletae Tablets	Para Phe Chlor 080/81/AP 144	
142	Clotribest and Lignocaine Ear drop	Clotri Ligno 080/81/AP 145	
143	Atorvastatin and Eetimibe Tablets	Ator Eze 080/81/AP 146	
144	Hydrocortisone Acetate and Lidocaine Suppositories	Hydro Lido 080/81/AP 147	
145	Mirabegron Extended Release Tablets	Mirab 080/81/AP 148	
146	Tolvaptan Tablets	Tolvap 080/81/AP 149	
147	Ciprofloxacin Oral Solution (Vet)	Cipro 080/81/AP 150	
148	Cinacalcet Tablet	Cinacal 080/81/AP 151	
149	Tetrabenazine Tablet	Tetrab 080/81/AP 152	
150	Gliclazide Extended Release Tablets	Glicla ER 080/81/AP 153	Monograph available in IP 2022 Addendum 2024
151	Bilastine Tablets	Bilas 080/81/AP 154	Monograph available in IP 2022 Addendum 2024
152	Fenbendazole Tablets [Vet]	Fenben 080/81/AP 156	
153	Empagliflozin and Linagliptin Tablets	Empa Lina 080/81/AP 157	
154	Fenbendazole Bolus [Vet]	Fenben B 080/81/AP 158	
155	Benfotiamine Capsules	Benfot 080/81/AP 159	
156	Prucalopride Tablets	Prucal 080/81/AP 160	
157	Thiocolchicoside Tablets	Thioco 080/81/AP 161	
158	Tetracycline Bolus	Tetra 080/81/AP 162	
159	(S)- Amlodipine Besylate and Losartan Tablets	S Amlo Losar 080/81/AP 163	
160	Oxytetracycline Bolus	Oxytetra 081/082/AP 164	

S.N	Product Name	Analytical Profile No.	Remarks
161	Bilastine Orodispersible Tablets	Bilas DT 081/082/AP 165	
162	Bilastine Oral Solution	Bilas OS 081/082/AP 166	
163	Oxyclonazide and Levamisole Bolus [Veterinary]	Oxyclo Levami B 081/082/AP 167	
164	Bedaquiline Tablets	Bedaq 081/082/AP 168	
165	Ciprofloxacin HCl Powder [Vet]	Ciprovet 081/082/AP 169	
166	Lurasidone HCl Tablets	Luras 081/082/AP 170	Subject to approval from DAC
167	Sulphamethoxazole & Trimethoprim Powder	Cotri 081/082/AP 171	Subject to approval from DAC
168	Meloxicam & Paracetamol Bolus	Para Melo 081/082/AP 172	Subject to approval from DAC
169	Finerenone Tablets	Finere 081/082/AP 173	Subject to approval from DAC
170	Mecobalamin Dispersible Tablets	Mecoba 081/082/AP 174	Subject to approval from DAC

ANNEX-6

Testing and analysis section

High performance liquid chromatography (HPLC)

Gas chromatography (GC)

Atomic absorption spectroscopy (AAS)

ANNEX 7

Microbiology Section

Biosafety Cabinet Class A2

Incubators

Washing Area

Autoclave

ANNEX-8

NML five year strategy drafted with the support of USAID PQM plus (sample pages)

नेपाल औषधि अनुसन्धानशालाको पञ्चवर्षीय रणनैतिक कार्ययोजना

(२०८१/८२-२०८५/८६)

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय

नेपाल औषधि अनुसन्धानशाला

१

विषय सूची

२

१.५.२ औषधि नियामक निकायका लागि विश्व स्वास्थ्य संगठनद्वारा स्थापित वैश्विक मापदण्ड विधि (WHO GBT) बमोजिमको विश्लेषण

विश्व स्वास्थ्य संगठनद्वारा स्थापित वैश्विक मापदण्ड विधि (WHO GBT) बमोजिमको विश्लेषण अनुसार हाल अनुसन्धानशालाको क्षमता न्यूनस्तर (maturity level 1) मा रहेको अवस्था।

२. दूरदृष्टी, ध्येय र रणनैतिक उद्देश्य (Vision, Mission and Strategic Objectives)

२.१.दूरदृष्टी (Vision)

जनस्वास्थ्यको सम्वर्धन, प्रवर्धन र सुरक्षा गर्न नेपाल सरकारको प्रमुख अंगको रूपमा औषधिको परीक्षण, अनुसन्धान तथा विश्लेषणका क्षेत्रमा अन्तर्राष्ट्रिय पहिचानको अनुसन्धानशाला।

२.२.ध्येय (Mission)

औषधिको अनुसन्धान, विश्लेषण र परीक्षणमा उत्कृष्टता हासिल गर्ने।

२.३.रणनैतिक उद्देश्यहरू (Strategic Objectives)

यस रणनैतिक कार्ययोजनाका रणनैतिक उद्देश्यहरू निम्नानुसार छन्:

१. औषधिको उच्चतम तहको गुणस्तर, सुरक्षा र प्रभावकारीता कायम गर्नकालागि आवश्यक नियम, कार्यविधि र मापदण्डको तर्जुमा गर्ने।
२. दिगो आर्थिक स्रोतको सुनिश्चितता गर्ने।
३. उपयुक्त सिप समिश्रण सहितको व्यावसायिक क्षमतावान दक्ष जनशक्ति विकास गर्ने।
४. अत्याधुनिक औजार तथा उपकरण सहितको भौतिक पूर्वाधार विकास गर्ने (Biosafety Level-II/III) साथै आन्तरिक नियन्त्रण प्रणाली लागु गर्ने।
५. विश्लेषण तथा परीक्षणको क्षमता र सेवाको दायरामा संस्थागत र गुणात्मक स्तर वृद्धि गर्नुका साथै सार्वजनिक सेवा प्रवाहमा सुशासन कायम गर्ने।
६. अनुसन्धानशालामा संचार प्रविधि सूचना व्यवस्थापन प्रणाली (Electronic Laboratory Management Information System-eLMIS) व्यवस्थित गर्ने।

२.४.रणनैतिक लक्ष्य (Strategic Goals):

रणनीतिका मुख्य लक्ष्यहरू निम्नानुसार छन् :

- सन् २०२४ सम्ममा भेटेरिनेरी, आयुर्वेद र वैकल्पिक चिकित्सा प्रणालीका औषधिको परीक्षण शुरु गर्ने,
- सन् २०२४ सम्ममा ISO 17025:2017 प्रमाणीकरण प्राप्त गरी गुणस्तरीयता र प्रभावकारी, विश्वसनीयता वृद्धि गर्ने,

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- सन् २०२४ सम्म WHO Prequalification कार्यक्रमले तय गरेका मापदण्ड पूरा गर्ने,
- सन् २०२५ सम्ममा WHO Prequalification प्रमाणपत्र प्राप्त गरी अन्तर्राष्ट्रिय मान्यता हासिल गर्ने,
- सन् २०२६ सम्ममा प्रविधिजन्य स्वास्थ्य सामग्रीको परीक्षण शुरु गर्ने,
- सन् २०२७ सम्ममा संघीयताको मर्म अनुरूप प्रदेश तहमा औषधि परीक्षण अनुसन्धानशाला स्थापनाको प्रारम्भ गर्ने,
- सन् २०२७ सम्ममा क्यान्सरको उपचारमा प्रयोग हुने cytotoxic औषधि र हर्मोनको परीक्षण गर्ने गरी परीक्षणको दायरा बढाउने,
- सन् २०२८ सम्ममा बायोलोजिकल्स र खोपको परीक्षण शुरु गर्ने।

२.५ रणनैतिक उद्देश्य र कार्यनीतिहरू :

रणनैतिक उद्देश्य	कार्यनीति
१. औषधिको उच्चतम तहको गुणस्तर, सुरक्षा र प्रभावकारीता कायम गर्नकालागि आवश्यक नियम, कार्यविधि र मापदण्डको तर्जुमा गर्ने।	१.१ औषधि ऐन, २०३५ को व्यवस्था बमोजिम औषधिको वैज्ञानिक अनुसन्धान, परीक्षण र विश्लेषण सम्बन्धी नियमावली तयार गरी लागु गर्ने। १.२ अनुसन्धानशालाका लागि आवश्यक विभिन्न मापदण्ड, निर्देशिका र आधारभूत कार्यविधि पुनरावलोकन गरी समसामयिक संशोधन गर्ने, नयाँ गर्ने। १.३ योजना, अनुगमन तथा मूल्यांकन सम्बन्धी कार्य सुदृढ र व्यवस्थित गर्ने। १.४ नेपाल औषधि अनुसन्धानशालाबाट प्रदान गरिने सेवालाई सन्दर्भ अनुसन्धानशाला/प्रयोगशालाको रूपमा विकास गर्ने कार्यविधि बनाई लागु गर्ने। १.५ अनुसन्धानशालाबाट प्रदान गरिने सेवालाई पारदर्शी, जवाफदेही र व्यावसायिक बनाउने।
२. दिगो आर्थिक स्रोतको सुनिश्चितता गर्ने।	२.१ अनुसन्धानशालालाई आर्थिक स्वायत्तता सहितको स्वतन्त्र निकायको रूपमा स्थापना गर्ने। २.२ अनुसन्धानशालाको सेवा शुल्क पुनरावलोकन गरी समय सापेक्ष बनाउने। २.३ सहयोगी दातृ निकाय र अन्य सरोकारवालाको समन्वयमा नयाँ स्रोत व्यवस्थापन गर्ने। २.४ यस रणनैतिक कार्ययोजनाको क्रियाकलापहरू संचालन गर्ने हरेक वर्ष बजेटसमेतको कार्ययोजना (AWPB) बनाई स्वास्थ्य तथा जनसंख्या मन्त्रालयबाट बजेटको सुनिश्चितता गर्ने।
३. उपयुक्त सिप समिश्रण सहितको व्यावसायिक क्षमतावान दक्ष जनशक्ति विकास गर्ने।	३.१ औषधि परीक्षण सेवाको बढ्दो चाप र मागलाई मध्यनजर गरी संगठन तथा व्यवस्थापन सर्वेक्षण (O&M) गर्ने। ३.२ सबै शाखा, ईकाई र जनशक्तिको स्पष्ट कार्यविवरण पुनरावलोकन गरी लागु गर्ने। ३.३ संलग्न जनशक्तिको लागि नियमित क्षमता र दक्षता विकासका कार्यक्रम संचालन गर्ने साथै अन्तर्राष्ट्रिय स्तरमा संचालन हुने तालिममा सहभागी गराउने। ३.४ कर्मचारीको पेशागत स्वास्थ्य र सुरक्षा (occupational safety) प्रवर्धन गर्ने।

१२

	३.५ कर्मचारीको लागि कार्यसम्पादनमा आधारित प्रोत्साहन प्रणाली लागु गर्नुका साथै जोखिम भत्ता, अतिरिक्त कार्य भत्ता (overtime) उपलब्ध गराउने । ३.६ पेशागत क्षमता विकासको लागि निरन्तर र नियमित औषधि अध्ययन (Continuous Pharmaceutical Education/Continuous Professional Development) प्रणालीको विकास गर्दै कार्यान्वयन गर्ने ।
४. अत्याधुनिक औजार तथा उपकरण सहितको भौतिक पूर्वाधार विकास गर्ने (Biosafety Level-II/III) साथै आन्तरिक नियन्त्रण प्रणाली लागु गर्ने ।	४.१ Biosafety level (BSL-II/III) सञ्चालन हुने गरी नयाँ अत्याधुनिक अनुसन्धानशाला भवन निर्माणका लागि गुरुयोजना तयार गरी कार्यान्वयन गर्ने । ४.२ अनुसन्धानशाला तत्काल प्रभावकारी संचालनका लागि प्राथमिकताका साथ आवश्यक बजेट, जनशक्ति र अन्य स्रोतसाधनको व्यवस्था गर्ने । ४.३ अनुसन्धानशालालाई आधुनिक प्रविधि, औजार, उपकरण सहित स्तरोन्नति गर्ने । ४.४ भण्डारण र आपूर्ति प्रणालीलाई व्यवस्थित गर्ने । ४.५ चालु अवस्थाका औजार तथा उपकरणको वर्षभरी नियमित उपलब्धता सुनिश्चित गर्ने । ४.६ पानी तथा बिजुलीको नियमित आपूर्ति तथा फोहरमैलाको उचित व्यवस्थापनको सुनिश्चितता गर्ने ।
५. विश्लेषण तथा परीक्षणको क्षमता र सेवाको दायरामा संस्थागत र गुणात्मक स्तर वृद्धि गर्नुका साथै सार्वजनिक सेवा प्रवाहमा सुशासन कायम गर्ने ।	५.१ परीक्षण दायरा विस्तार गरी नयाँ सेवा जस्तै बायोलोजिकल्स, भ्याक्सिन, आयुर्वेद चिकित्सा प्रणालीका औषधि, प्रविधिजन्य स्वास्थ्य सामग्री परीक्षण क्रमशः वृद्धि गर्दै जाने । ५.२ गुणस्तरीय सेवा प्रदान गर्ने मद्दत गर्ने संस्थागत पद्धति र सुशासन प्रणालीको प्रवर्धन गर्ने । ५.३ सार्वजनिक र निजी क्षेत्रका औषधि परीक्षण प्रयोगशाला र अनुसन्धान केन्द्रसँग कार्यमूलक समन्वय र सहकार्य स्थापना गर्ने । ५.४ औषधि परीक्षण अनुसन्धानशालालाई प्रदेश तहसम्म विस्तार गरी सार्वजनिक सेवा प्रवाह सुदृढ गर्ने । ५.५ कुशल प्रयोगशाला अभ्यासको अनुगमन (GLP Audit) गर्ने तथा कुनै औषधिको वैज्ञानिक अनुसन्धान र विकासको लागि स्थापना हुने कुनै स्वदेशी तथा विदेशी संस्था वा व्यक्तिको लागि आवश्यक मापदण्ड तोकिन गरी मान्यताका लागि स्वास्थ्य तथा जनसंख्या मन्त्रालयलाई सिफारिस गर्ने । ५.६ करार परीक्षण तथा विश्लेषण (contract testing and analysis) लाई आवश्यक कार्यविधि बनाई मान्यता दिने । ५.७ तेस्रो पक्ष परीक्षण स्वीकृति (third party testing authorization) प्रदान गर्ने ।
६. अनुसन्धानशालामा संचार प्रविधि सूचना व्यवस्थापन प्रणाली (Electronic	६.१ अनुसन्धानशालामा सञ्चार प्रविधि सूचना व्यवस्थापन प्रणाली (Electronic Laboratory Management Information System- eLMIS) लागु गर्ने ।

Laboratory Management Information System-eLMIS) व्यवस्थित गर्ने ।	६.२ सूचनाको आदान प्रदान गरी नियमनकारी निकायको अभिन्न अंग बन्नुका साथै नीति योजनामा समसामयिक सुधारको लागि पृष्ठपोषण गर्ने

३. रणनीतिको कार्यान्वयन

रणनीतिको प्रभावकारी कार्यान्वयनका लागि निम्नानुसारका मार्गदर्शनहरूको अवलम्बन गरिने छ :

ध्येय केन्द्रित	अनुसन्धानशालाको सुधारका लागि गरिने हरेक कृयाकलापहरू औषधि परीक्षण र अनुसन्धानमा उत्कृष्टता हासिल गर्ने गरी कार्यान्वयन गरिने छ ।
समन्वय र सहकार्य	संघ र प्रदेशसँगको समन्वय र सरोकारवाला सरकारी, गैरसरकारी र निजी क्षेत्रका उद्योग, प्रयोगशाला र अनुसन्धान केन्द्रहरूसँग सहकार्य गरी कार्यान्वयन गरिनेछ ।
स्रोतको परिचालन	स्वास्थ्य तथा जनसंख्या मन्त्रालय र सहयोगी दातृराष्ट्र, राष्ट्रिय- अन्तर्राष्ट्रिय संघसंस्थाहरूबाट प्राप्त हुने स्रोतको प्रभावकारी परिचालन गरिने छ ।
कार्ययोजना	रणनीतिमा प्रस्ताव गरिएका कृयाकलापहरूको कार्यान्वयन गर्ने निश्चित क्रियाकलाप, समयावधि, जिम्मेवार व्यक्ति र आवश्यक स्रोत सहितको वार्षिक कार्ययोजना तयार गरी कार्यान्वयन गरिनेछ ।
क्रमबद्धता र प्राथमिकता	पञ्चवर्षीय रणनीतिमा प्रस्ताव गरिएका क्रियाकलापहरूलाई महत्व, आवश्यकता तथा सम्भाव्यताका आधारमा प्राथमिकीकरण गरी कार्यान्वयन गरिनेछ ।
दक्षता तथा क्षमता विकास	कर्मचारीहरूलाई नयाँ प्रविधि, अनुसन्धान, गुणस्तर सुनिश्चितता र नियमनकारी अभ्यासहरूको कार्यान्वयनका सम्बन्धमा तालिम प्रदान गरी रणनैतिक कार्ययोजनाकार्यान्वयन गर्न सक्षम बनाइनेछ ।
सूचना, सञ्चार तथा प्रविधि	प्रभावकारी सञ्चार रणनीतिको माध्यमबाट सरोकारवालाहरूलाई रणनीतिको कार्यान्वयन र उपलब्धीहरूबारे सुसूचित गरिनेछ । कृत्रिम बौद्धिकता (Artificial Intelligence-AI) जस्ता अत्याधुनिक सूचना प्रविधिको प्रयोगमा जोड दिइनेछ ।
निरन्तर सुधार	रणनैतिक क्रियाकलापको समयानुकूल परिमार्जन, समीक्षा तथा अद्यावधिक गर्नका लागि प्रभावकारी पृष्ठपोषण प्रणाली विकास गरी बदलिँदो परिवेश र प्रविधि अनुसार सुधारका कार्यहरू गरिनेछ ।
जोखिम व्यवस्थापन	सम्भावित बाधा तथा चुनौतीहरूको पूर्वानुमान गरी आकस्मिक योजना मार्फत जोखिम व्यवस्थापन सम्बन्धि क्रियाकलापहरू कार्यान्वयनको निरन्तरता सुनिश्चित गरिनेछ ।
सुशासन र नेतृत्व	उपयुक्त निर्णय लिने प्रकृया, मार्गदर्शन र जवाफदेहीता स्थापित गर्ने स्पष्ट कार्यविभाजन र जिम्मेवारी तोकिनेछ ।

अनुसूची २ : क्रमागत विकास

पहिलो वर्ष (२०२४)

उपलब्ध गुणस्तर नीति, निर्देशिका, आधारभूत कार्यविधिहरूको पहिचान गरी दस्तावेज बनेको, योजना, अनुगमन र गुणस्तर सुनिश्चितताकालागि जिम्मेवार व्यक्ति तथा ईकाईहरू तोकिएको, विश्व स्वास्थ्य संगठनको असल प्रयोगशाला अभ्यासको मार्गदर्शन अनुसार अर्धवार्षिक स्व:मूल्यांकन गरिएको , आधुनिक उपकरणहरू जडान गरिएको, ISO 17025:2017 प्रमाणीकरणका लागि संस्थागत योजना तयार भएको, निजी क्षेत्रका औषधि परीक्षण प्रयोगशाला र उद्योगहरूसँग सहकार्य गरिएको, हाल उपलब्ध भौतिक संरचनाको मर्मत तथा विस्तारका लागि प्राविधिक मूल्यांकन गरिएको र पुरानो काम नलाग्ने उपकरण तथा फर्निचरहरू लिलाम गरिएको,आवश्यक औजार तथा उपकरणहरूको पहिचान गरिएको, नियमित संचालनका लागि आवश्यक रसायन तथा सामग्रीहरूको आवश्यकता पहिचान गरिएको, नियमित मर्मत सम्भार योजना तयार भएको, कार्यरत जनशक्ति र शाखाहरूको कार्यबोझ मूल्यांकन (संगठन तथा व्यवस्थापन सर्वेक्षण) गरी संगठन संरचनाको ढाँचा तयार गरिएको, अनुसन्धानशालाका कर्मचारीहरूलाई पेशागत स्वास्थ्य र सुरक्षा सम्बन्धी तालिम प्रदान गरिएको, अनुसन्धानशालाको अलग बजेट कोड सहित वित्तीय स्वायत्तताका लागि पैरवी सुरु गरिएको, एकीकृत अनुसन्धानशाला सूचना व्यवस्थापन प्रणाली सुरु भएको हुनेछ ।

दोश्रो वर्ष (२०२५)

आवश्यक सबै नीति, मापदण्ड र कार्यविधि तयार गरी लागु गरिएको, योजना, अनुगमन तथा गुणस्तर सुनिश्चितता सम्बन्धी कार्य गर्ने शाखाहरूलाई साधन स्रोत सहित सशक्त बनाईएको, अनुगमन तथा मूल्यांकन योजना र आवधिक समीक्षा संचालन भएको , ISO 17025:2017 प्रमाणीकरण प्रमाणपत्र लिएको, WHO Prequalification लिने प्रक्रिया सुरु भएको, भौतिक संरचना तथा उपकरणको व्यवस्था, हाल प्रयोगमा रहेको भवन मर्मत तथा विस्तार कार्य पूरा भएको, अनुसन्धानशालाको गुरुयोजना तयार गर्नका लागि विज्ञ नियुक्त भएको, बहुवर्षीय खरिद योजना तयार गरिएको, भण्डार कक्ष व्यवस्थित बनाईएको, सरकारी र गैरसरकारी संस्थाहरूसँग समन्वय गरिएको, सबै जनशक्तिको लागि कार्यविवरण तयार गरिएको, कार्यसम्पादनमा आधारित प्रोत्साहन प्रणाली लागु गरिएको, सिप विकास तालिम कार्यक्रम संचालन गरिएको, निजी क्षेत्रका प्रयोशालासँग समन्वय बैठक सन्चालन गरिएको, प्रदेश तहमा औषधि परीक्षण अनुसन्धानशाला स्थापनाका लागि पैरवी गरिएको ,अनुसन्धानशालामा एकीकृत अनुसन्धानशाला व्यवस्थापन सूचना प्रणाली व्यवस्थित गरिएको, निजी प्रयोगशालाबीच अन्तरप्रयोगशाला तुलनात्मक विश्लेषण कार्यक्रम (Interlaboratory comparison (ILC)) आयोजना गरिएको, प्रविधियुक्त स्वास्थ्य सामग्री, खोप, cytotoxic औषधि तथा biologicals परीक्षणको पूर्वाधार विकास गरिएको हुनेछ ।

तेश्रो वर्ष (२०२६)

नियमावली तयार गरी लागु गरिएको , WHO Prequalification हासिल गरिएको , आयुर्वेद र वैकल्पिक औषधिको परीक्षण सुरु गरिएको, गुरुयोजना तयार गरी कार्यान्वयन गरिएको , HPLC, LC-MS-MS, र GC-MS जस्ता आधुनिक उपकरणहरू खरिद गरी सेवा विस्तार गरिएको , पानी प्रशोधन र फोहरमैला व्यवस्थापनका लागि अत्याधुनिक प्लान्ट जडान भएको, अनुसन्धानशालालाई अलग बजेट शीर्षक सहित बजेट तथा कार्यक्रम प्राप्त गरी वित्तीय स्वायत्तता हासिल भएको , अनिवार्य क्षमता परीक्षणका माध्यमबाट निरन्तर सिप विकास गर्दै पेशागत स्वास्थ्यको सुरक्षाका लागि निःशुल्क स्वास्थ्य बीमा गरेको , प्रदेश तहमा औषधि परीक्षण अनुसन्धानशाला स्थापनाको लागि पहलकदमी गरेको , गुरुयोजनाको अन्तिम मस्यौदा तयार भई स्वीकृतिको लागि पेश भएको हुनेछ ।

चौथो वर्ष (२०२७)

अनुसन्धानशालामा क्यान्सर विरुद्धका औषधि, खोप, हर्मोन, माईक्रोबायोलोजिकलको परीक्षणका लागि उपकरण तथा दक्ष जनशक्ति तयार भएको, द्रुत र प्रभावकारी प्रतिवेदन प्रणाली स्थापीत भएको, अनुसन्धानात्मक कार्यहरू सुचारु भएको, भौतिक पूर्वाधारको गुरुयोजना स्वीकृत भै कार्यान्वय सुरु भएको हुनेछ । अनुसन्धानशालाको नियमावली तर्जुमा पश्चात करार परीक्षण (contract testing) सुरुवात भएको हुनेछ ।

पाँचौ वर्ष (२०२८)

पर्याप्त रूपमा आवश्यक जनशक्ति उपलब्ध भएको, अनुसन्धानशालामा खोपको परीक्षण सुरुवात भएको, प्रदेश तहमा औषधि परीक्षण अनुसन्धानशालाको स्थापना तथा रिफरल प्रयोगशालाको रूपमा स्थापित भएको, प्रभावकारी आर्थिक व्यवस्थापन भएको, माइक्रोबायोलोजीकल, बायोलोजिकल, एन्टीक्यान्सर, हर्मोनल र मेडिकल उपकरण परीक्षण अनुसन्धानशालाको लागि सेवाको प्रारम्भिक कार्यको थालनी भएको हुनेछ।

ANNEX-9

Training conducted by NML with the support of USAID PQM plus for ISO 17025 accreditation

1. Laboratory Quality Risk Management Training

2. Training on quality control of anti-tuberculosis medicines

3. Workshop on the implementation of standard operating procedure of NML

4.Workshop on the implementation of quality manual of NML

5.Training on measurement of uncertainity

6.Training on overview of requirement for health technology products

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औषधि व्यवस्था विभाग

राष्ट्रिय औषधि प्रयोगशाला

बिजुलीबजार, काठमाडौं

info@nml.gov.np, Contact no. 4781269