Annexure I

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
1.	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		
2.	Capsules	Assay + Identification+Weight Variation	20	20		50
		Dissolution	6	6	12	
		Uniformity of Content	10	20		
		Disintegration	6	6		
3.	Liquid Oral	Identification+Assay	**2**	**2**		5
		Fill volume variation	10	10		
4.	Powder for Oral Liquid	Identification+Assay	**3**	**3**		5
		Fill volume variation	10	10		
5.	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		

Prepared by:	Reviewed by:	Approved by:
Name: Purna Kumari Shrestha	Name: Saraswati Dangol	Name: Bharat Bhattarai
Designation: Quality Control Inspector	Designation: Sr. Quality Controller	Designation: Act. Director
Date: 26 Nov 2025	Date: 28 Nov 2025	Date: 30 Nov 2025

CONTROLLED COPY

S.N.	Dosage form	Test Parameter	Quantities Required			
			Initial Test	Repeat Test 1	Repeat Test 2	Control Sample
		Sterility test (for small volume ≤ 100 ml	20	20		
		Bacterial Endotoxin (if required)	5	5		
6.	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		
7.	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		
8.	Ointment/ Cream	Identification+Assay	3	3		5
		Fill weight variation	10	10		
		Microbiological Assay if required	2 tubes per API	2 tubes per API		
9.	Herbal Powder/Liquid/ Paste	Identification+Assay	3	3		1
		Fill volume/Fill weight variation	10	10		
		Microbiology	3	3		

Note: Content uniformity not applicable for multivitamins.

Prepared by:	Reviewed by:	Approved by:
Name: Purna Kumari Shrestha	Name: Saraswati Dangol	Name: Bharat Bhattarai
Designation: Quality Control Inspector	Designation: Sr. Quality Controller	Designation: Act. Director
Date: 26 Nov 2025	Date: 28 Nov 2025	Date: 30 Nov 2025

CONTROLLED COPY