

Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical Profile of Oxyclozanide Bolus

Analytical Profile No.: Oxyclo B 082/083 AP 176

Oxyclozanide Bolus contains not less than 90.0% and not more than 110.0% of the stated amount of Oxyclozanide.

Usual Strength: 1000 mg

1. Identification:

Weigh accurately the sample equivalent to 100 mg of Oxyclozanide. Dissolve in methanol to produce 100 ml. Filter the solution and dilute 5 ml of the filtrate to 50 ml with methanol. The solution shows maximum absorbance at about 300 nm.

2. Assay: *Determine by UV Spectrophotometry*

2.1 Methanol, Acidified: To 900 ml of methanol, add 18 ml of glacial acetic acid, and dilute to 1000 ml with water.

2.2 Test solution: Weigh the contents of 5 boli and crush. Weigh the powder equivalent to 60 mg of Oxyclozanide in a 100 ml dry volumetric flask, add 60 ml of acidified methanol, and boil gently on a water bath. Shake continuously for 20 minutes to dissolve. Cool the sample solution, make up the volume with the acidified methanol, and mix. Dilute 5 ml of the filtrate to 100 ml with acidified methanol.

2.3 Procedure: Measure the absorbance of the resulting solution at the maximum at about 300 nm. Calculate the content of Oxyclozanide taking 254 as the specific absorbance (1%, 1 cm) at 300 nm.

3. Other tests: As per Pharmacopoeial requirements.