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

Analytical profile of Piperazine Hydrate Oral Solution (Veterinary)

Analytical Profile No.: Pipera 080/81/AP 138

Piperazine Hydrate Oral solution contains not less than 92.5 % and not more than 107.5 % of Piperazine Hydrate.

Usual Strength: Each ml contains

Piperazine hydrate IP 450 mg

1. Identification:

To 1 ml add 5 ml of 2M hydrochloric acid with stirring, 1 ml of a freshly prepared 50% w/v solution of sodium nitrite, cool in ice for 15 minutes, induce crystallization, wash the crystalline precipitate with water and dry at 105˚ C. The crystals melt at about 159˚ C.

2. Assay: *Determine by Gravimetric Method*

2.1 Procedure:

1. Weigh a quantity of sample equivalent to 0.2 gm. of Piperazine Hydrate, add 3.5 ml of 0.5 M sulphuric acid and 10 ml of water, add 100 ml of picric acid solution.
2. Heat on a water bath for 15 minutes, allow to stand for 1 hour and filter through sintered glass crucible (Porosity No.4). Wash the residue with successive quantities, each 10 ml of a mixture of volumes of a saturated solution of picric acid and water until the washings are free from sulphate.
3. Wash the residue with five quantities, each 10 ml, of ethanol and dry to constant weight at 105 C

Note: 1 gram of the residue is equivalent to 0.3567 gram of Piperazine Hydrate

3. Other Test: As per Pharmacopoeial Requirement.