

Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section
Analytical profile of Ibuprofen and Paracetamol Suspension

Analytical Profile No.: Ibu ParS 073/074/ AP 011

Usual Strength: Each 5 ml contains
Ibuprofen IP 100 mg
Paracetamol IP 125 mg

1. Identification:

1.1. Ibuprofen: Extract a quantity of the powdered tablet containing 0.5 g of Ibuprofen with 20 ml of acetone, filter and evaporate the filtrate to dryness in the current of air without heating. The residue obtained in the test after recrystallization from light petroleum (40 °C to 60 °C) melts at about 75 °C.

1.2. Paracetamol

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests:

- 2. pH:** As per manufacturer's specification
- 3. Wt/ml:** As per manufacturer's specification

4. Assay

4.1 Assay of Ibuprofen

Weigh accurately a quantity of the suspension containing about 100 mg of Ibuprofen, extract with 60 ml of chloroform for 15 minutes and filter through a sintered - glass crucible of porosity 3. Wash the residue with three quantities, each of 10 ml, of chloroform and gently evaporate the filtrate just to dryness on water bath. Dissolve the residue in 100 ml of ethanol (95%), previously neutralized to phenolphthalein solution as indicator and titrate with 0.1 M sodium hydroxide using phenolphthalein solution as indicator.

1 ml of 0.1 Sodium Hydroxide is equivalent to 0.02063 g of C₁₃H₁₈O₂

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4.2 Assay of Paracetamol: *Determine by liquid chromatography*

4.2.1 Solvent Mixture: 0.4 volume of formic acid, 15 volumes of methanol and 85 volumes of water.

4.2.2 Test Solution: Shake and weigh a quantity of the suspension containing about 62.5 mg of Paracetamol in 100 ml of volumetric flask. Add about 70 ml of the solvent mixture, dissolve by sonicating for about 10 minutes. Cool to room temperature and dilute to 100 ml with the solvent mixture. Centrifuge the resulting solution. Dilute 2 ml of this solution to 50 ml with the solvent mixture.

4.2.3 Standard Solution: Weigh accurately about 31.25 mg of Paracetamol and transfer into 50 ml volumetric flask. Add about 40 ml of the solvent mixture, dissolve by sonicating for about 10 minutes. Cool to room temperature and dilute to 50 ml with the solvent mixture. Dilute 2 ml of this solution to 50 ml with the solvent mixture.

4.2.4 Chromatographic system

Column: 4.6 mm × 25 cm, 5 µm packing (Shim-Pack Gist, C18)

Flow rate: 1 ml/min

Injection volume: 20 µl

Wavelength: 243 nm

Mobile phase: 1.60 g butanesulphonate in 1000 ml of solvent mixture.

4.2.5 Procedure: Inject the reference solution five/six times and test solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates. The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0%. Calculate the content of paracetamol in the suspension.

5. Other tests: As per pharmacopoeial requirement.