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

Analytical profile of Chlorzoxazone & Paracetamol Tablets

Chlorzoxazone & Paracetamol Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Chlorzoxazone & Paracetamol.

Analytical Profile No.: Chl Para 075/076/AP 025

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference solution.

2. Dissolution Test (Paracetamol & Chlorzoxazone):

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of Phosphate buffer pH 6.8

Speed and Time: 75 rpm and 60 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution:

2.3.1 Paracetamol Reference Solution: Weigh accurately about 100 mg of Paracetamol RS in 100ml volumetric flask, add 70ml of methanol, sonicate for 5 minutes and make up the volume with same solvent.

2.3.2 Chlorzoxazone Reference Solution: Weigh accurately about 100 mg of Chlorzoxazone RS in 100ml volumetric flask, add 70ml of methanol, sonicate for 5 minutes and make up the volume with same solvent.

2.3.3 Combined Reference Solution: Pipette 2ml of Paracetamol & Chlorzoxazone standard solution in 100ml volumetric flask and dilute with dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution. Calculate the percent release of Chlorzoxazone & Paracetamol.

2.5 Limit: D. NLT 70% of the stated amount

3. Assay(Paracetamol & Chlorzoxazone):

3.1 Test Solution: Weigh individually 20 tablets & crush the tablets into fine powder. Weigh accurately a quantity of powder equivalent to 100 mg of Chlorzoxazone, add 70ml of methanol, sonicate for 15 minutes and dilute to 100 ml with same solvent, filter. Dilute 2ml of resulting solution to 100ml with mobile phase.

3.2 Reference Solution:

3.2.1 Paracetamol Reference Solution: Weigh accurately about 100 mg of Paracetamol RS in 100ml volumetric flask, add 70ml of methanol, sonicate for 5 minutes and make up the volume with same solvent.

3.2.2 Chlorzoxazone Reference Solution: Weigh accurately about 100 mg of Chlorzoxazone RS in 100ml volumetric flask, add 70ml of methanol, sonicate for 5 minutes and make up the volume with same solvent.

3.2.3 Combined Reference Solution: Pipette 2ml of Paracetamol & Chlorzoxazone standard solution in 100ml volumetric flask and dilute with mobile phase.

3.3 Chromatographic system

Column: Octyldecylsilane (C18), (250*4.6 mm), 5 µm

Flow rate: 1.5 ml/min

Detector: UV Detector

Wavelength: 271 nm

Injection volume: 20 µl

Mobile phase: Acetonitrile: buffer (65:35)

Buffer (Phosphate buffer pH 3.0): 0.05M disodium hydrogen phosphate of pH 3.0 adjusting pH with dilute phosphoric acid.

3.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Silodosin.

4. Other tests: As per pharmacopoeial requirements.