

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

Analytical profile of Disodium Hydrogen Citrate Syrup

Analytical Profile No.: DCS 075/076/AP035

Disodium Hydrogen Citrate Syrup contains not less than 90.0% and not more than 110.0% of the stated amount of Disodium Hydrogen.

1. Identification:

1.1. Disodium hydrogen citrate

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.

2. pH: As per the manufacturer's specification

3. Wt/ml: As per the manufacturer's specification

4. Assay: *By liquid chromatography*

4.1 Test Solution: Weigh accurately the sample equivalent to 1.40 g of Disodium Hydrogen Citrate and transfer into 100 ml volumetric flask. Add about 60 ml of HPLC water and sonicate for about 10 minutes. Cool the solution to room temperature and make up the volume to 100 ml with HPLC water. Dilute further 10 ml of the resulting solution to 100 ml with HPLC water & mix.

4.2 Reference Solution: Weigh accurately about 140 mg of Disodium Hydrogen Citrate WS and transfer into 100 ml volumetric flask. Dissolve it with 60 ml HPLC water by sonicating for 10 minutes and make up the volume with HPLC water.

4.3 Chromatographic System

Column : (150 × 4.6) mm; ODS (C18)

Temperature : 30 °C

Wavelength : UV 210 nm

Flow rate : 1 ml/ min.

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Injection volume : 20 µl

Mobile phase A: 0.05% Phosphoric Acid in Water

Mobile phase B: Acetonitrile

Gradient Programming

Time (Min)	Mobile Phase A (%)	Mobile Phase B (%)
0	100	0
6.5	100	0
7.0	50	50
11	50	50
12	100	0
30	100	0

4.4 Procedure: Inject the reference solution five/six times and sample 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%. Measure the peak response. Calculate the content of Disodium Hydrogen Citrate in the syrup.

5. Other tests: As per pharmacopoeial requirement.