DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Disodium Hydrogen Citrate Syrup

Analytical Profile No.: DCS 075/076/AP035

Disodium Hydrogen Citrate Syrup contains not less than 90 % and not more than 110 % of the stated amount of Disodium Hydrogen Citrate.

1. Identification:
The retention time of the major peak in the chromatogram of test solution corresponds to that of the reference solution as obtained in assay.

Tests:

2. pH: 4 - 5.5

3. Wt/ml: As per manufacturer's instruction.

4. Assay: *Determine 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. Filter through 0.2-micron filter paper.

4.2 Reference Solution: Weigh accurately about 140 mg of Disodium Hydrogen Citrate reference standard 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. Filter through 0.2-micron filter paper.

4.3 Chromatographic system:

Column:	C18, 150 × 4.6 mm
Injection volume:	20 µl
Flow rate:	1 ml/ min
Wavelength:	210 nm

Column Temperature: 30 ºC

Detector: UV

Mobile phase A: 0.05% Phosphoric Acid in Water

Mobile phase B: Acetonitrile

Use gradient program as shown below:

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 20 µl of reference solution five times. 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 in not more than 2.0%. Inject 20 µl of test solution and calculate the content of Disodium Hydrogen Citrate in the syrup.

5. Other tests: As per pharmacopoieal requirement.