Sulphacetamide Sodium

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

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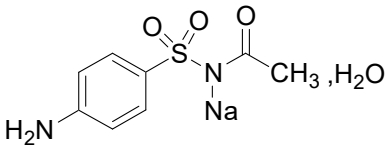
Change **to**: **Sulphacetamide Sodium**



$C_8H_9N_2NaO_3S,H_2O$ Mol. Wt. 254.2

Sulphacetamide Sodium is acetamide, *N*-[(4-aminophenyl)sulphonyl] monosodium salt; monohydrate.

Sulphacetamide Sodium contains not less than 99.0 per cent and not more than 100.5 per cent of $C_8H_9N_2NaO_3S$, calculated on the anhydrous basis.

Category. Antibacterial.

Description. A white crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *sulphacetamide sodium IPRS* or with the reference spectrum of sulphacetamide sodium.

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

C. Dissolve 0.5 g in 10 ml of *dilute hydrochloric acid* (solution A) and divide into two parts. To one part of solution A, add 2 ml of *trinitrophenol solution*; a very heavy flocculent or almost gelatinous precipitate is formed. To the other part of solution A, add 3 drops of *formaldehyde solution*; a white precipitate is formed and it changes to orange on standing (distinction from sulphamethoxypyridazine).

D. A 5 per cent w/v solution gives the reaction (A) of sodium salts (2.3.1).

Tests
pH (2.4.28). 8.0 to 9.5, determined in a 5.0 per cent w/v solution in *water*.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.2 g of the substance under examination in the mobile phase and dilute to 100.0 ml with the mobile phase.

Reference solution (a). A solution containing 0.0002 per cent w/v of *sulphacetamide sodium IPRS* and 0.0004 per cent w/v of *sulphanilamide IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.02 per cent w/v of *sulphacetamide sodium IPRS* and 0.005 per cent w/v of *sulphanilamide IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as YMC-Pack ODS-AQ),
- mobile phase: a mixture of 89 volumes of *water*, 10 volumes of *methanol* and 1 volume of *glacial acetic acid*,
- flow rate: 0.8 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Name	Relative retention time
Sulphanilamide[1]	0.6
Sulphacetamide	1.0

[1] *p*-Aminobenzenesulphonamide

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to sulphanilamide and sulphacetamide is not less than 5.0 in the chromatogram obtained with reference solution (b), the tailing factor is not more than 1.5 for sulphacetamide and the relative standard deviation for replicate injections is not more than 2.0 per cent for sulphacetamide in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of the any peak corresponding to sulphanilamide is not more than twice the area of the corresponding peak in the chromatogram obtained with reference solution (a) (0.2 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent) and the sum of the areas of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent).

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Water (2.3.43). 6.0 per cent to 8.0 per cent, determined on 0.2 g.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 20 mg of the substance under examination in *water* and dilute to 100.0 ml with *water*.

Reference solution. A 0.02 per cent w/v solution of *sulphacetamide sodium IPRS* in *water*.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as YMC-Pack ODS-AQ),
- mobile phase: A. 1 per cent v/v solution of *glacial acetic acid* in *water*,
  B. *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 0.8 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	90	10
5	90	10
9.5	10	90
9.6	90	10
14	90	10

Inject the reference solution. The test is not valid unless the tailing factor is between 0.9 to 1.8 and the relative standard deviation for replicate injections is not more than 0.5 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_8H_9N_2NaO_3S$.

Storage. Store protected from light and moisture.