Sulphacetamide Eye Drops

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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 Eye Drops**

Sulphacetamide Sodium Eye Drops

Sulphacetamide Eye Drops is a sterile solution of Sulphacetamide Sodium in Purified Water. It may contain a suitable buffers, stabilizers and antimicrobial agent.

Sulphacetamide Eye Drops contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of sulphacetamide sodium, $C_8H_9N_2NaO_3S,H_2O$.

Usual strengths. 10 per cent w/v; 20 per cent w/v; 30 per cent w/v.

Identification

A. Dilute a volume of the Eye Drops containing 1 g of Sulphacetamide sodium in 25 ml of *water*, adjusted to pH 4-5 with *6 M acetic acid* and filter. Wash the precipitate with *water* (use for test B and C) and dry at 105° for 2 hours. The melting range (2.4.21) of the residue is between 180° to 184°.

B. Place 0.5 g of the precipitate in the test tube and heat gently until it boils. An oily liquid, a characteristic odour of *acetamide* is evolved and condenses on the walls of the test tube (distinction from the sublimates of sulphadiazine, sulphamerazine and sulphamethazine, which are solids at room temperature).

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

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a suitable volume of the eye drops containing 0.2 g of Sulphacetamide Sodium with the mobile phase and dilute to 100.0 ml of 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).

Other tests. Comply with the tests stated under Eye Drops.

Sterility (2.2.11). Complies with the test for sterility.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a suitable volume of the eye drops containing 100 mg of Sulphacetamide Sodium to 100.0 ml with 20 per cent v/v solution of *methanol*. Further dilute 3.0 ml of the solution to 100.0 ml with the same solvent.

Reference solution (a). Transfer 50 mg of *sulphacetamide sodium IPRS* to a 40-ml centrifuge tube, add 10.0 ml of 20 per cent v/v solution of *methanol* and mix using a vortex mixer for 3 minutes. Add 7.5 ml of *heptane* and mix using a vortex mixer for 3 minutes. Centrifuge and discard the upper heptane layer. Dilute 3.0 ml of the solution to 50.0 ml with 20 per cent v/v solution of *methanol.* Further dilute 1.0 ml of the solution to 10.0 ml with the same solvent.

Reference solution (b). A 0.003 per cent w/v solution of *sulphanilamide IPRS* in reference solution (a).

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as MicroBondapak C18),
- mobile phase: a mixture of 89 volumes of *water*, 10 volumes of *methanol* and 1 volume of *glacial acetic acid*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 100 µl.

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 3.0 in the chromatogram obtained with reference solution (b), the column efficiency is not less than 1500 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_8H_9N_2NaO_3S,H_2O$ in the eye drops.

Storage. Store protected from light and moisture, at a temperature between 8° to 15°.

Labelling. The label states (1) the name and concentration of any antimicrobial agent used; (2) that it is not meant for injection; (3) that the solution should be used within one month of opening the container; (4) that the solution should not be used if it is dark brown in colour; (5) that it should not be allowed to freeze.