Nitrofurazone Ointment

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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.	

Nitrofurazone Ointment

Nitrofural Ointment

Nitrofurazone Ointment is Nitrofurazone in a suitable water-miscible base.

Nitrofurazone Ointment contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of nitrofurazone, $C_6H_6N_4O_4$.

NOTE – Avoid exposure at all times to direct sunlight, excessive heat, strong fluorescent lighting, and alkaline materials.

Usual strength. 0.2 per cent w/w.

Identification

Dissolve 400 mg of *potassium hydroxide* in a mixture of 9.5 ml of *ethanol* and 0.5 ml of *methanol*. Immediately before use, dilute to 100 ml with *dimethylformamide*. To 10 ml of the solution, add a quantity of the ointment containing 10 µg of Nitrofurazone and mix: a purple colour is produced.

Tests

Completeness of solution. Dissolve 1 g in 9 ml of *water* to form a clear solution.

Other tests. Comply with the tests stated under Ointments.

Assay. Determine by liquid chromatography (2.4.14).

NOTE—Protect all solutions from light that contain nitrofurazone.

Test solution. Weigh and disperse a quantity of the ointment containing 1 mg of Nitrofurazone in 0.2 ml of *dimethylformamide* and 25 ml of *ethanol,* with the aid of ultrasound for 35 minutes with intermittent shaking, and dilute to 100.0 ml with *water,* mix and filter.

Reference solution. Dissolve 50 mg of *nitrofurazone IPRS* in 10 ml of *dimethylformamide* and dilute to 50.0 ml with *ethanol.* Dilute 10.0 ml of the solution to 100.0 ml with *ethanol.* Transfer 10.0 ml of the solution to a 100-ml volumetric flask, add 15 ml of *ethanol* and dilute to 100.0 ml with *water*.

Chromatographic system

- a stainless steel column 30 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (10 µm),
- mobile phase: a mixture of 79 volumes of *water*, 20 volumes of *acetonitrile* and 1 volume of *a* buffer prepared by diluting 10 ml of *triethylamine* with 80 ml of *water,* cautiously add 8 ml of *orthophosphoric acid* and dilute to 100 ml with *water*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 365 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless 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.

Inject the reference solution and the test solution.

Calculate the content of $C_6H_6N_4O_4$ in the ointment.

Storage. Store protected from light and avoid exposure to strong fluorescent lighting and excessive heat.