Povidone-Iodine 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. 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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Povidone-Iodine Eye Drops

Povidone-Iodine Eye Drops are either a sterile solution of Povidone-Iodine in purified water or they are prepared by the interaction between Iodine and Povidone in purified water.

Povidone-Iodine Eye Drops contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of iodine, I.

Usual strength. 5 per cent w/v.

Description. A clear brown solution.

Identification

A. Dilute 1 ml to 10 ml with *water* and add 1 ml of the resulting solution to a mixture of 1 ml of *starch mucilage* and 9 ml of *water*; a deep blue colour is produced.
B. Dilute 4 ml to 10 ml with *water*; add dropwise *0.1 M sodium thiosulphate* until the colour of the iodine is just discharged. Reserve 5 ml of the resulting solution for test C. To 5 ml of the resulting solution add 10 ml of *1 M hydrochloric acid* and 5 ml of *dilute potassium dichromate solution*; a red precipitate is produced.
C. To 5 ml of the solution reserved in test B, add 2 ml of *ammonium cobaltothiocyanate solution* previously acidified with *5 M hydrochloric acid*; a blue precipitate is produced.

Tests

pH (2.4.24). 3.5 to 6.5.

Iodide. Not more than 0.6 per cent, determined by the following method.
Dilute the eye drops suitably with *water* to get a solution containing 0.5 per cent w/v of Povidone-Iodine and add *sodium metabisulphite* until the colour of iodine is disappeared. Add 25.0 ml of *0.1 M silver nitrate*, 10 ml of *nitric acid* and 5 ml of 10 per cent w/v solution of *ferric ammonium sulphate*. Titrate with *0.1 M ammonium thiocyanate*. Carry out a blank titration. Calculate the percentage content of total iodine and subtract the percentage content of available iodine obtained in the Assay to obtain the percentage content of iodide.

1 ml of *0.1 M silver nitrate* is equivalent to 0.01269 g of I.

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

Assay. To a measured volume containing about 0.25 g of Povidone-Iodine; add 10 ml of *0.1 M hydrochloric acid* and sufficient *water* to produce 30 ml. Titrate immediately with *0.01 M sodium thiosulphate*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.01 M sodium thiosulphate* is equivalent to 0.001269 g of I.

Storage. Store protected from light.

Labelling. The label states the strength in terms of percentage w/v of Povidone Iodine.

4.2. General Reagents

Ammonium Cobaltothiocyanate Solution: Dissolve 3.75 g of *cobalt nitrate* and 15.0 g of *ammonium thiocyanate* in sufficient *water* to produce 100 ml.

Use within a day of preparation