Bepotastine Tablets

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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.	

Bepotastine Tablets

Bepotastine Besilate Tablets; Bepotastine Besylate Tablets.

Bepotastine Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of, bepotastine besilate, $C_{21}H_{25}ClN_2O_3.C_6H_6O_3S$.

Usual strength. 10 mg.

Identification

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.

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium.900 ml of *water*.

Speed and time.50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Dilute the filtrate with the mobile phase to obtain a solution containing 0.00022 per cent w/v of Bepotastine Besilate.

Reference solution. A 0.0011 per cent w/v solution of *bepotastine besilate IPRS* in the dissolution medium. Dilute 2.0 ml of the solution to 10.0 ml with the mobile phase.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- column temperature: 40º,
- mobile phase: a 0.1 per cent w/v solution of *1-pentane sulphonic acid sodium salt* in a mixture of 70 volumes of *0.05 M potassium dihydrogen phosphate*, adjusted to pH 3.0 and 30 volumes of *acetonitrile,*
- flow rate: 1 ml per minute,
- spectrophotometer set at 260 nm,
- injection volume: 50 µl.

NOTE – Flow rate may be adjusted so that the retention time of bepotastine is about 6 minutes.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 5000 theoretical plates, the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 1.5 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{21}H_{25}ClN_2O_3.C_6H_6O_3S$ in the medium.

Q. Not less than 80 per cent of the stated amount of $C_{21}H_{25}ClN_2O_3.C_6H_6O_3S$.

Uniformity of dosage unit (2.5.4). Meet the requirements.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Internal standard solution. A 0.0222 per cent w/v solution of *ethyl paraben IPRS* in *acetonitrile.*

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 20 mg of Bepotastine Besilate in the mobile phase, with the aid of ultrasound with intermittent shaking, add 10.0 ml of the internal standard solution and dilute to 50.0 ml with the mobile phase. Dilute 2.0 ml of the solution to 10.0 ml with the mobile phase.

Reference solution. Dissolve 20 mg of *bepotastine besilate IPRS* in the mobile phase with the aid of ultrasound with intermittent shaking, add 10.0 ml of the internal standard solution and dilute to 50.0 ml with the mobile phase. Dilute 2.0 ml of the solution to 10.0 ml with the mobile phase.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- column temperature: 40º,
- mobile phase: a 0.1 per cent w/v solution of *1-pentane sulphonic acid sodium salt* in a mixture of 70 volumes of *0.05 M potassium dihydrogen phosphate*, adjusted to pH 3.0 and 30 volumes of *acetonitrile,*
- flow rate: 1 ml per minute,
- spectrophotometer set at 260 nm,
- injection volume: 20 µl.

NOTE – Flow rate may be adjusted so that the retention time of bepotastine is about 6 minutes.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to the bepotastine and the internal standard is not less than 5.0 and the relative standard deviation of the ratio of the peak area of bepotastine to that of the internal standard, for the replicate injections is not more than 1.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{21}H_{25}ClN_2O_3.C_6H_6O_3S$ in the tablet, using ratio the peak area of bepotastine to that of the internal standard.

Storage. Store protected from moisture, at temperature not exceeding 30º.