Desloratadine 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.	

Desloratadine Tablets

Desloratadine Tablets contain not less than 93.0 per cent and not more than 105.0 per cent of the stated amount of desloratadine, $C_{19}H_{19}ClN_2$.

Usual strengths. 5 mg; 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. 500 ml of *0.1 M hydrochloric acid*,
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium, filter. Measure the absorbance of the filtrate, suitably diluted with the medium, if necessary, at the maximum at about 282 nm (2.4.7). Calculate the content of $C_{19}H_{19}ClN_2$ in the medium from the absorbance obtained from 0.001 per cent w/v solution of *desloratadine IPRS* in the dissolution medium

Q. Not less than 80 per cent of the stated amount of $C_{19}H_{19}ClN_2$ in the medium.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE—Protect the solutions from light.

Solvent mixture. 10 volumes of *water* and 90 volumes of *methanol*.

Test solution. Disperse a quantity of the powdered tablets containing 20 mg of Desloratadine in 10 ml of the *water*, with the aid of ultrasound, add 50 ml of *methanol*, stir for 60 minutes and dilute to 100.0 ml with the *methanol*, centrifuge a portion of the solution and use the supernatant.

Reference solution (a). A solution containing 0.0002 per cent w/v, each of, *desloratadine IPRS* and *desloratadine related compound A IPRS* in the solvent mixture.

Reference solution (b). A 0.001 per cent w/v solution of *desloratadine IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octylsilane bonded to porous silica (3 µm) (Such as Ace C8)
- column temperature: 35°,
- mobile phase: A. a buffer solution prepared by dissolving 4.35 g of *dipotassium hydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.2 with *dilute orthophosphoric acid*.
  B. *acetonitrile*,
  C. *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 241 nm,
- injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Mobile phase C (per cent v/v)
0	70	15	15
12	70	15	15
30	40	30	30
45	40	30	30
47	70	15	15
55	70	15	15

Name	Relative retention time
Dechloro desloratadine[1*]	0.37
Desloratadine	1.0
Dehydro desloratadine [2*]	1.4
Desloratadine related compound F[3]	1.8
Loratadine[4]	2.7

[*]Process impurity, included for identification only. Not to be calculated and included in total degradation product.
[1]6,11-Dihydro-11-(piperidin-4-ylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine;
[2]8-Chloro-11-(piperidin-4-ylidene)benzo[5,6]cyclohepta[1,2-*b*]pyridine;
[3]8-Chloro-6,11-dihydro-11-(N-formyl-4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine;
[4]8-Chloro-6,11-dihydro-11-(1-ethoxycarbonylpiperidin-4-ylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine.

Inject reference solution (a) and (b). The test is not valid unless the column efficiency is not less than 1500 theoretical the tailing factor is not more than 3.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a) and the signal-to-noise ratio is not less than 10 in the chromatogram obtained with reference solution (b).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak due to desloratadine related compound F is not more than 0.3 times the area of the corresponding in the chromatogram obtained with reference solution (a) (0.3 per cent), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). Ignore any peak with an area less than 0.05 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Uniformity of Dosage unit (2.5.4). Comply with the tests stated under Tablets.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

NOTE—Protect the solutions from light.

Solvent mixture. 90 volumes of *methanol* and 10 volumes of *water*.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 50 mg of Desloratadine in 25 ml of *water*, with the aid of ultrasound, add 125 ml of *methanol*, stir for not less than 60 minutes. Allow the solution to cool to room temperature and dilute to 250.0 ml with *methanol*. Centrifuge a portion of the solution. Dilute 5.0 ml of the supernatant to 50.0 ml with the solvent mixture.

Reference solution. A 0.002 per cent w/v solution of *desloratadine IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with nitrile groups bonded to porous silica (5 µm) (Such as Alltima CN)
- column temperature: 30°,
- mobile phase: a mixture of 80 volumes of a buffer solution prepared by dissolving 4.35 g of *dipotassium hydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.0 with *orthophosphoric acid* and 20 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 241 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 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 $C_{19}H_{19}ClN_2$ in the tablets.

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