Eltrombopag 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. 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 arnd-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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Eltrombopag Tablets

Eltrombopag Olamine Tablets

Eltrombopag Tablets contain Eltrombopag Olamine equivalent to not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of Eltrombopag, $C_{23}H_{27}N_3O_7$.

Usual strengths. 12.5 mg; 25 mg; 50 mg; 75 mg.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *eltrombopag olamine IPRS* or with the reference spectrum of eltrombopag olamine.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
Medium. Medium. 900 ml of 0.05 M potassium phosphate buffer solution pH 6.8 prepared by dissolving 6.81 g of *potassium dihydrogen orthophosphate* and 1.45 g of *potassium hydroxide* in 1000 ml of *water*, adjusted to pH 6.8 with *potassium hydroxide solution* or *orthophosphoric acid* and add 5 ml of *polysorbate 80*, stir gently and mix, [*Note – Do not add foam reducing agents to the dissolution medium*]
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, dilute suitably if necessary with the medium, using 0.5 cm cell for 12.5 mg and 0.1 cm cell for 25 mg; 50 mg; 75 mg, at the maximum at about 424 nm (2.4.7). Calculate the content of $C_{23}H_{27}N_3O_7$in the medium from the absorbance obtained from a solution of known concentration of *eltrombopag olamine IPRS* in the dissolution medium.

Calculate the contents of $C_{23}H_{27}N_3O_7$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{23}H_{27}N_3O_7$.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Carry out the test protected from light. Store the solution at 2° to 8° and use within 3 hours of preparation.

Solvent mixture. Equal volumes of *dimethylformamide* and *water*.

Test solution. Disperse a quantity of the powdered tablets containing 25 mg of Eltrombopag in solvent mixture with the aid of ultrasound for 10 minutes and mechanical shaking for 25 minutes, and dilute to 500.0 ml with the solvent mixture, filter.

Reference solution (a). A solution of *eltrombopag olamine IPRS* containing 0.005 per cent w/v of eltrombopag in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) 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 (5 µm),
- column temperature: 30°,
- sample temperature: 5°,
- mobile phase: A. 0.1 per cent v/v of *trifluoroacetic acid* in *water*,
  B. 0.1 per cent v/v of *trifluoroacetic acid* in *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 250 nm,
- injection volume: 30 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	50	50
20	35	65
25	10	90
30	10	90
31	50	50
40	50	50

Name	Relative retention time
Eltrombopag	1.0
Eltrombopag imputity C[1]	1.08
Eltrombopag impurity B[2*]	1.23

*Process impurity included for identification only and not included in the calculation of total degradation products.
[1]3'-{(2Z)-2-[1-(3,4-Dimethylphenyl)-3-methyl-5-oxo-1,5-dihydro-4H-pyrazol-4-ylidene)-1-hydroxyhydrazinyl)-2'-hydroxy-3-biphenylcarboxylic acid,
[2]2^5,3^5-Bis{(2Z)-2-[1-(3,4-dimethylphenyl)-3-methyl-5-oxo-1,5-dihydro-4H-pyroazol-4-ylidene]hydrazinyl}-2^6,3^4-dihydroxy[1^1,2^1:2^3,3^1:3^3,4^1-quaterphenyl]-1^3,4^3-dicarboxylic acid.

Inject reference solution (b). 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 5.0 per cent.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to eltrombopag impurity C is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 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 (b) (0.2 per cent) and the sum of areas of all the secondary peaks is not more than 1.5 times the area of principal peak in the chromatogram obtained with reference solution (b) (1.5 per cent).

Uniformity of dosage units (2.5.4). Complies with the test stated under Uniformity of dosage units.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances with following modifications.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{23}H_{27}N_3O_7$ in the tablets.

1 mg of Eltrombopag Olaminein, $C_{25}H_{22}N_4O_4.2(C_2H_7NO)$ is equivalent to 0.784 mg of Eltrombopag (as free acid), $C_{23}H_{27}N_3O_7$.

Labelling. The label states the strength in terms of the equivalent amount of Eltrombopag.

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