Eltrombopag Olamine

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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

Description	Details
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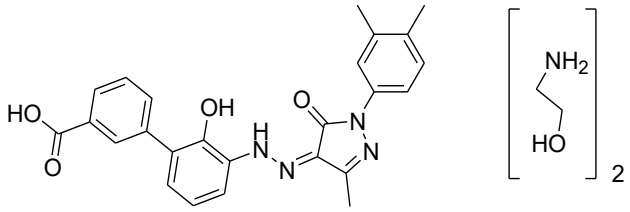
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Eltrombopag Olamine

Eltrombopag Diethanolamine



$C_{25}H_{22}N_4O_4$. $2(C_2H_7NO)$ Mol. Wt. 564.7

Eltrombopag olamine is 3'-{(2Z)-2-[1-(3,4-dimethylphenyl)-3-methyl-5-oxo-1,5-dihydro-4H-pyrazol-4-ylidene]hydrazine}-2'-hydroxy-3-biphenylcarboxylic acid -2-aminoethanol (1:2).

Eltrombopag olamine contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{25}H_{22}N_4O_4$. $2(C_2H_7NO)$, calculated on the anhydrous and solvent free basis.

Category. Thrombopoietin receptor agonist.

Description. A red to brown powder.

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 the reference solution.

Tests

Related substances. Determine by liquid chromatography (2.4.14).

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

Test solution. Dissolve 24 mg of the substance under examination in the solvent mixture with the aid of ultrasound with simultaneous swirling and dilute to 100.0 ml with the solvent mixture.

Reference solution. A 0.0024 per cent w/v solution of *eltrombopag olamine 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 5 cm × 2.0 mm, packed with octadecylsilane bonded to porous silica (3 µm) (such as Luna C18 (2)),
- column temperature: 40°,
- mobile phase: A. 0.05 per cent v/v of *trifluoroacetic acid* in *water*,
  B. 0.05 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: 3 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
8	5	95
10	5	95
10.1	100	0
13	100	0

Name	Relative retention time	Correction factor

Eltrombopag	1.0	--
Eltrombopag imputity A[1]	1.08	0.83
Eltrombopag impurity B[2]	1.64	1.11

[1]5'-chloro-3'-{2Z)-2-[1-(3,4-dimethylphenyl)-3-methyl-5-oxo-1,5-dihydro-4H-pyrazol-4-ylidene]hydrazinyl}-2'-hydroxy[1,1'-biphenyl]-3-carboxylic 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 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 5.0 per cent.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to eltrombopag impurity B is not more than 5 times the area of the principal peak in the chromatogram obtained with the reference solution (0.5 per cent), the area of any peak corresponding to eltrombopag impurity A is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of areas of all the secondary peaks is not more than 6 times the area of principal peak in the chromatogram obtained with reference solution (a) (0.6 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with the reference solution (0.05 per cent).

Sulphated ash (2.3.18). Not more than 0.2 per cent.

Water (2.3.43). Not more than 0.8 per cent, determined on 0.25 g. (Use 30-40 ml of Hydranal solvent prepared by adding 25 ml of stabilized tetrahydrofuran and 3 ml of hydranal base).

Assay. Determine by liquid chromatography (2.4.14),

Note: Use polypropylene HPLC vials for injection.

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

Test solution. Dissolve 24 mg of the substance under examination in the solvent mixture with the aid of ultrasound with simultaneous swirling and dilute to 100.0 ml with the solvent mixture.

Reference solution. A 0.024 per cent w/v solution of *eltrombopag olamine IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 3 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (3 µm) (such as Luna C18 (2)),
- column temperature: 40°,
- mobile phase: a mixture of 35 volumes of 0.05 per cent v/v of *trifluoroacetic acid* in *water* and 65 volumes of 0.05 per cent v/v of *trifluoroacetic acid* in *acetonitrile*,
- flow rate: 3 ml per minute,
- spectrophotometer set at 250 nm,
- injection volume: 5 µl.

Inject the reference solution. The test is not valid unless 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 $C_{25}H_{22}N_4O_4$. $2(C_2H_7NO)$.

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

Solubility: Freely soluble in *dimethyl sulfoxide*, soluble in *ethanol (95 per cent)* and slightly soluble in *water*.