Pazopanib 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 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.	

Pazopanib Tablets

Pazopanib Hydrochloride Tablets

Pazopanib Tablets contain Pazopanib Hydrochloride equivalent to not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of, pazopanib, $C_{21}H_{23}N_7O_2S$.

Usual strengths. 200 mg; 400 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 (a).

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.05 M sodium acetate*, adjusted to pH 4.5, containing 0.75 per cent w/v *sodium lauryl sulphate*,
Speed and time. 75 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, suitably diluted with the dissolution medium, if necessary, in a 0.5 cm cell at about 270 nm (2.4.7). Calculate the content of $C_{21}H_{23}N_7O_2S$ in the medium from the absorbance obtained from a solution of *pazopanib hydrochloride IPRS* in the dissolution medium containing 0.00176 per cent w/v of *pazopanib*.

Q. Not less than 75 per cent of the stated amount of $C_{21}H_{23}N_7O_2S$.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Prepare the solutions immediately before use.

Solvent mixture. 50 volumes of *acetonitrile*, 50 volumes of *water* and 0.1 volumes of *trifluoroacetic acid*.

Test solution. Disperse a quantity of the powdered tablets containing 1 g of pazopanib in 300 ml of solvent mixture, with the aid of ultrasound, with intermittent shaking and dilute to 500.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 100.0 ml in the solvent mixture, filter.

Reference solution (a). A solution of *pazopanib hydrochloride IPRS* containing 0.01 per cent w/v of *pazopanib* in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with the solvent mixture. Dilute 1.0 ml of the solution to 20.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with triacontyl silane (C30) bonded to porous silica (3 µm) (such as Develosil RP Aqueous-3),
- column temperature: 35°,
- mobile phase: A. a mixture of 100 volumes of *water* and 0.1 volumes of *trifluoroacetic acid*,
  B. a mixture of 100 volumes of *acetonitrile* and 0.1 volumes of *trifluoroacetic acid*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 268 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	90	10
1	90	10
31	46	54
33	90	10
40	90	10

Name	Relative retention time
Pazopanib	1.0
Pazopanib dimer[1*]	1.13
Pazopanib trimer[2*]	1.63

*Process impurity included for identification only, not to be calculated and included in total degradation products.
[1]5-((4-((2,3-dimethyl-2*H*-indazol-6-yl)(methyl)amino)pyrimidin-2-yl)amino)-*N*-((5-((4-((2,3-dimethyl-2*H*-indazol-6-yl)(methyl)amino)pyrimidin-2-yl)amino)-2-methylphenyl)sulphonyl)-2-methylbenzenesulphonamide,
[2]N-(4-(bis(5-((4-((2,3-dimethyl-2*H*-indazol-6-yl)(methyl)amino)pyrimidin-2-yl)amino)-2-methylphenyl)methyl)phenyl)-5-((4-((2,3-dimethyl-2*H*-indazol-6-yl)(methyl)amino)pyrimidin-2-yl)amino)-2-methylbenzenesulphonamide.

NOTE — A small peak at relative retention time about 1.02 is occasionally seen in reference solutions and test solution after storage. This is a degradation product of pazopanib and does not interfere with the quantitation of pazopanib.

Inject the reference solution (a) and (b). The test is not valid unless the test is not valid unless the resolution between the peaks due to pazopanib and pazopanib dimer not less than 3.0, the tailing factor is not more than 2.0, the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a) and the signal-to-noise ratio is not less than 10.0 in the chromatogram obtained with reference solution (b).

Inject the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than (0.5 per cent), calculated by area normalization. Ignore any peak at a relative retention time of about 1.02 and any peak with an area less than 0.1 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 the following modifications.

Inject reference solution (a). The test is not valid unless the test is not valid unless the resolution between the peaks due to pazopanib and pazopanib dimer not less than 3.0, the tailing factor is not more than 2.0.

Inject reference solution (a) and test solution.

Calculate the content of $C_{21}H_{23}N_7O_2S$ in the tablets.

1 mg of pazopanib hydrochloride, $C_{21}H_{23}N_7O_2S$,HCl is equivalent to 0.923 mg of pazopanib, $C_{21}H_{23}N_7O_2S$.

Storage. Store at a temperature not exceeding 30°.

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