Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Pazopanib Hydrochloride

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

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

Description	**Details**
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
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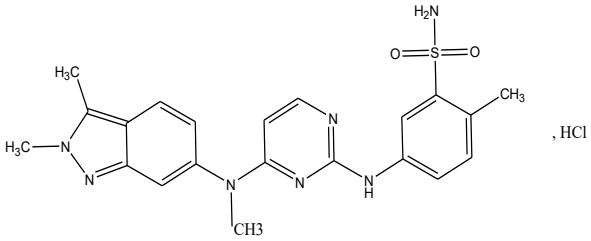
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Pazopanib Hydrochloride



$C_{21}H_{23}N_7O_2S,HCl$ Mol. Wt. 474.0

Pazopanib Hydrochloride is 5-((4-((2,3-dimethyl-2*H*-indazol-6-yl)(methyl)amino)pyrimidin-2-yl)amino)-2-methylbenzenesulphonamide hydrochloride.

Pazopanib Hydrochloride contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{21}H_{23}N_7O_2S,HCl$, calculated on the anhydrous and solvent free basis.

Category. Anticancer.

Description. A White to slightly yellow powder.

CAUTION — Pazopanib Hydrochloride is cytotoxic; extra care required to prevent inhaling particles and exposing the skin to it.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *pazopanib hydrochloride IPRS* or with the reference spectrum of Pazopanib Hydrochloride.

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).

C. It gives reaction (A) of chlorides (2.3.1).

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 70 volumes of mobile phase A and 30 volumes of mobile phase B.

Test solution. Dissolve 20 mg of the substance under examination in the solvent mixture with the aid of ultrasound and dilute to 100.0 ml with the solvent mixture.

Reference solution (a). A 0.02 per cent w/v solution of *pazopanib hydrochloride IPRS* in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml in the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml in the solvent mixture.

Reference solution (c). A solution containing 0.00024 per cent w/v, each of, *pazopanib dimer IPRS* and *pazopanib trimer IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml in reference solution (a).

Reference solution (d). Dilute 5.0 ml of reference solution (b) to 10.0 ml in the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with end-capped alkyl amide group bonded to porous silica (3.5 µm) (such as Zorbax Bonus-RP),
- column temperature: 40°,
- mobile phase: A. a 0.1 per cent v/v solution of *trifluoroacetic acid* in *water*,
  B. *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 268 nm,
- injection volume: 5 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	80	20
12	44	56
12.1	80	20
20	80	20

Name	Relative retention time
Pazopanib	1.0
Pazopanib dimer[1]	1.3
Pazopanib trimer[2]	1.7

[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.

Inject reference solution (b), (c) and (d). The test is not valid unless the resolution between the peaks due to pazopanib and pazopanib dimer is not less than 1.5 in the chromatogram obtained with reference solution (c), the tailing factor not more than 2.0, the relative standard deviation for replicate injections is not more than 5.0 per cent, for principal peak, in the chromatogram obtained with reference solution (b) and the signal to noise ratio is not less than 10 in the chromatogram obtained with reference solution (d).

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to pazopanib dimer and pazopanib trimer, each of, is not more than 1.2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.12 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 (b) (0.1 per cent) and the sum of the areas of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Water (2.3.43). Not more than 1.0 per cent, determined on 0.1 g.

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

Inject reference solution (a) and (c). The test is not valid unless the resolution between the peaks due to pazopanib and pazopanib dimer is not less than 1.5 in the chromatogram obtained with reference solution (c) and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_{21}H_{23}N_7O_2S$,HCl.

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