Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Sunitinib Maleate

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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).

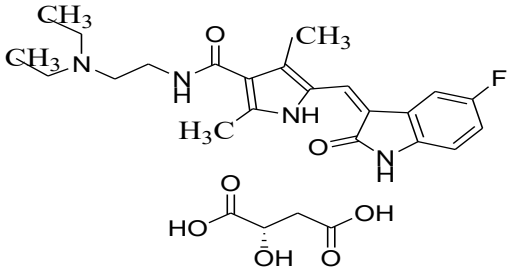
Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to 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**
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
Tentative effective date of monograph	April, 2028
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Sunitinib Malate



$C_{22}H_{27}FN_4O_2$, $C_4H_6O_5$ Mol. Wt. 532.6

Sunitinib Malate is butanedioic acid, hydroxy-, (2*S*)-, compound with *N*-[2-(diethylamino)ethyl]-5-[(*Z*)-(5 fluoro-1,2-dihydro-2-oxo-3*H*-indol-3-ylidine)methyl]-2,4-dimethyl-1*H*-pyrrole-3 carboxamide (1:1).

Sunitinib Malate contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{22}H_{27}FN_4O_2$, calculated on the anhydrous, solvent free basis.

Category. Antineoplastic agent

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

Description. A yellow to orange powder.

Identification

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

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

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Protect the solutions from light.

Solvent mixture. 70 volumes of mobile phase A and 30 volumes of *acetonitrile*.

Test solution. Dissolve a quantity of the substance under examination containing 20 mg sunitinib (free base) in the solvent mixture and dilute to 100.0 ml with the solvent mixture.

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

Reference solution (b). A 0.002 per cent w/v solution of *sunitinib malate impurity D IPRS* in reference solution (a).

Reference solution (c). 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 octadecylsilane bonded to porous silica (5 µm) (such as Supelco Discovery C18),
- column temperature: 45°,
- mobile phase: A. a mixture of 77 volumes of *0.05 M ammonium acetate* and 23 volumes of *0.05 M acetic acid*, adjusted to pH 5.0 with *0.05 M acetic acid*,
  B. *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 268 nm,

– injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	90	10
36	37	63
37	90	10
52	90	10

Name	Relative retention time
L-Malic acid	0.10
Sunitinib malate impurity A[1]	0.67
Sunitinib malate impurity C[2]	0.91
Sunitinib malate impurity D[3]	0.96
Sunitinib	1.00
Sunitinib malate impurity F[4]	1.03
Sunitinib malate impurity B[5]	1.23
Sunitinib malate impurity E[6]	1.68

[1](*E*)-*N*-[2-(diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3-H-indol- 3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-carboxamide.
[2](*Z*)-*N*-[2-(ethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3-H-indol- 3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide.
[3](*Z*)-*N*-[2-(diethylazinoyl)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3-H-indol- 3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide.
[4](*Z*)-5-[(5-fluoro-2-oxo-1,2-dihydro-3-H-indol-3-ylidene)methyl]- 2,4-dimethyl-1H-pyrrole-3-carboxamide.
[5](*Z*)-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4- dimethyl-1H-pyrrole-3-carboxylic acid.
[6](*Z*)-3-[(3,5-dimethyl-1H-pyrrol-2-yl)methylene]-5-fluoro-1,3- dihydro-2H-indol-2-one.

Inject reference solution (b) and (c). The test is not valid unless the resolution between the peaks due to sunitinib and sunitinib malate impurity D is not less than 1.0 per cent in the chromatogram obtained with reference solution (b) and the signal-to-noise ratio for the principal peak is not less than 10.0 in the chromatogram obtained with reference solution (c).

Inject the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to sunitinib malate impurity A and sunitinib malate impurity C, each of, is not more 0.4 per cent, the area of any peak corresponding to sunitinib malate impurity D, sunitinib malate impurity E and sunitinib malate impurity F, each of, is not more 0.15 per cent, the area of any peak corresponding to sunitinib malate impurity B is not more than 0.6 per cent, the area of any other secondary peak is not more than 0.1 per cent and the sum of the areas of all the secondary peaks is not more than 1.2 per cent. Ignore any peak due to malic acid and with an area less than 0.05 per cent, calculated by area normalization.

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

Water (2.3.43). Not more than 0.75 per cent, determined on 0.5 g.

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

Inject reference solution (a). The test is not valid unless the tailing factor is not less than 0.9 and not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{22}H_{27}FN_4O_2$.

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

Solubility. Sunitinib Malate: Soluble in *dimethylsulphoxide*, slightly soluble in *water* and practically insoluble in *n-heptane*.