Sunitinib Capsules

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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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Sunitinib Capsules

Sunitinib Malate Capsules

Sunitinib Capsules contain sunitinib malate equivalent to not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of sunitinib, $C_{22}H_{27}FN_4O_2$.

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

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

Identification

A. *Test solution.* Dissolve a quantity of the mixed content of the capsules in *methanol* to obtain a solution containing 0.002 per cent w/v of sunitinib.

Reference solution. A solution of *sunitinib malate IPRS* containing 0.002 per cent w/v of sunitinib in *methanol.*

When examined in the range 200 nm to 600 nm, the UV spectrum obtained with the test solution is comparable with that obtained with reference solution.

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).
NOTE — Protect the solutions from light.
Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid,*
Speed and time. 50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter. Dilute a suitable volume of the filtrate with the dissolution medium, if necessary and measure the absorbance (2.4.7) of the resulting solution at the maximum at about 430 nm. Calculate the content of $C_{22}H_{27}FN_4O_2$ in the medium from the absorbance obtained from a solution of sunitinib malate IPRS in the dissolution medium having known concentration of *sunitinib* similar to that of the test solution.

Q. Not less than 75 per cent of the stated amount of $C_{22}H_{27}FN_4O_2$.

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. Disperse a quantity of the mixed content of the capsules containing 20.0 mg of sunitinib in the solvent mixture with the aid of ultrasound for 10 minutes and dilute to 100.0 ml with the solvent mixture, filter.

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.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]	0.65
Sunitinib malate impurity C[2]	0.91
Sunitinib malate impurity D[3]	0.97
Sunitinib (Retention time: about 17 minutes)	1.00
Sunitinib malate impurity B[5]*	1.23

* Process impurity, included for identification only. Not to be calculated and included in the total degradation product.
[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-3H-indol-3-ylidene)methyl]-2,4- dimethyl-1H-pyrrole-3-carboxylic acid.

Inject reference solution (b) and (c). The test is not valid unless the resolution between the peaks due to sunitinib and sunitinib impurity D is not less than 1.5 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 is not more 0.5 per cent, the area of any peak corresponding to sunitinib malate impurity C is not more 0.6 per cent, the area of any other 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 1.0 per cent. Ignore any peak due to malic acid and with an area less than 0.05 per cent, calculated by area normalization.

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

Other tests. Comply with the tests stated under Capsules.

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 1.0 per cent.

Inject reference solution (a) and the test solution.

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

1 mg of sunitinib malate $C_{22}H_{27}FN_4O_2$. $C_4H_6O_5$ is equivalent to 0.7482 mg of sunitinib, $C_{22}H_{27}FN_4O_2$.

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

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