# Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

## Sumatriptan Tablets

**Published on:** 11.06.2026 **Last date for comments:** 27.07.2026

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. | |

# Sumatriptan Tablets

Sumatriptan Succinate Tablets

Sumatriptan Tablets contain Sumatriptan Succinate equivalent to not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of, Sumatriptan, $C_{14}H_{21}N_3O_2S$.

**Usual strengths**. 25 mg; 50 mg; 100 mg.

## Identification

Disperse a quantity of the powdered tablets containing the equivalent of 70 mg of sumatriptan with 10 ml of *methanol,* with the aid of ultrasound for 5 minutes, filter. Evaporate the filtrate and dry under reduced pressure for 1 hour. On the residue, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *sumatriptan succinate IPRS* or with the reference spectrum of sumatriptan succinate.

## Tests

**Dissolution** (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *water*.
Speed and time. 50 rpm and 15 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, suitably diluted with the dissolution medium if necessary, to obtain a solution containing 0.0011 per cent w/v of sumatriptan, at maximum at about 282 nm (2.4.7). Calculate the content of $C_{14}H_{21}N_3O_2S$ in the medium from the absorbance obtained from a solution of *sumatriptan succinate IPRS* in the dissolution medium containing 0.0011 per cent w/v of sumatriptan.

Q. Not less than 75 per cent of the stated amount of $C_{14}H_{21}N_3O_2S$.

**Sumatriptan Impurities A and H**. Determine by liquid chromatography (2.4.14).

*Test solution*. Disperse a quantity of the powdered tablets containing 0.14 g of sumatriptan in *0.1 M hydrochloric acid* with the aid of ultrasound and dilute to 100.0 ml with *0.1 M hydrochloric acid*, filter.

*Reference solution*. A solution of *sumatriptan succinate IPRS* containing 0.00105 per cent w/v of sumatriptan in *0.1 M hydrochloric acid*.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with silica (5 µm) (such as Spherisorb silica S5W),
- mobile phase: a mixture of 10 volumes of *10 M ammonium acetate* and 90 volumes of *methanol*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 282 nm,
- injection volume: 20 µl.

| Name | Relative retention time | Correction factor |
|---|---|---|
| Sumatriptan | 1.0 | --- |
| Sumatriptan impurity A[1] | 2.2 | 0.5 |
| Sumatriptan impurity H[2] | 3.0 | --- |

[1]1-[3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1*H*-indol-5-yl]methyl]-1*H*-indol-5-yl]-*N*- methylmethanesulphonamide,
[2]1-[3-[2-(dimethylamino)ethyl]-1-[[3-[2-(dimethylamino)ethyl]-1*H*-indol-5-yl]methyl]-1*H*-indol-5-yl]-*N*- methylmethanesulphonamide.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject the reference solution and the test solution. Run the chromatogram 5 times the retention time of the principal peak. In the chromatogram obtained with the test solution, the area of any peak corresponding to sumatriptan impurity A is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.75 per cent) and the area of any peak corresponding to sumatriptan impurity H is not more than 0.4 times the area of the principal peak in the chromatogram obtained with the reference solution (0.3 per cent).

**Related substances**. Determine by liquid chromatography (2.4.14).

*Test solution*. Disperse a quantity of the powdered tablets containing 0.14 g of sumatriptan in *0.1 M hydrochloric acid* with the aid of ultrasound and dilute to 100.0 ml with *0.1 M hydrochloric acid*, filter.

*Reference solution*. A solution of *sumatriptan succinate IPRS* containing 0.0042 per cent w/v of sumatriptan in *0.1 M hydrochloric acid*. Dilute 1.0 ml of the solution to 10.0 ml with *0.1 M hydrochloric acid*.

Chromatographic system

- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Spherisorb ODS 1),
- mobile phase: a mixture of 75 volumes of a solution prepared by dissolving 0.97 g of *dibutylamine*, 0.735 g of *orthophosphoric acid* and 2.93 g of *sodium dihydrogen orthophosphate* in1000 ml of *water,* adjusted to pH 7.5 with *10 M sodium hydroxide* and 25 volumes of *acetonitrile,*
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 282 nm,
- injection volume: 20 µl.

| Name | Relative retention time |
|---|---|
| Sumatriptan impurity B[1] | 0.6 |
| Sumatriptan impurity D[2] | 0.7 |
| Sumatriptan impurity C[3] | 0.8 |
| Sumatriptan | 1.0 |

[1]*N*-methyl-1-[3-[2-(methylamino)ethyl]-1*H*-indol-5-yl]methanesulphonamide,
[2]*N*,*N*-dimethyl-2-[5-[(methylsulphamoyl) methyl]-1*H*-indol-3-yl] ethan-1-amine *N*-oxide.
[3]1-[3-[2-(dimethylamino)ethyl]-1-(hydroxymethyl)-1*H*-indol-5-yl]-N-methylmethanesulphonamide,

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject the reference solution and the test solution. Run the chromatogram 4 times the retention time of the principal peak. In the chromatogram obtained with the test solution, the area of any peak corresponding to sumatriptan impurity B, sumatriptan impurity C and sumatriptan impurity D, each of, is not more than 2.5 times the area of the principal peak in the chromatogram obtained with the reference solution (0.75 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.3 per cent). Ignore any peak with an area less than 0.33 times the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent).

The sum of the impurities (in the test for sumatriptan impurities A and H and the Related substances) is not more than 2.0 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).

*Test solution.* Weigh and powder 20 tablets. Disperse a quantity of the powder containing 0.14 g of sumatriptan in *0.1 M hydrochloric acid* with the aid of ultrasound and dilute to 100.0 ml with *0.1 M hydrochloric acid*, filter. Dilute 1.0 ml of the filtrate to 10.0 ml with *0.1 M hydrochloric acid*.

*Reference solution.* A solution of *sumatriptan succinate IPRS* containing 0.014 per cent w/v of sumatriptan in *0.1 M hydrochloric acid*.

Use chromatographic system as described under Related substances.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject the reference solution and the test solution.

Calculate the content of $C_{14}H_{21}N_3O_2S$ in the tablets.

1 mg of sumatriptan succinate, $C_{14}H_{21}N_3O_2S$, $C_4H_6O_4$ is equivalent to 0.714 mg of sumatriptan, $C_{14}H_{21}N_3O_2S$.

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

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