Sildenafil Injection

Published on: 01.08.2024 **Last date for comments:** 14.09.2024

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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. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. 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	2.0
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	06.06.2024
Draft revision published on IPC website for public comments	01.08.2024
Further follow-up action as required.	

Sildenafil Injection

Sildenafil Citrate Injection

Sildenafil Injection is a sterile solution of Sildenafil Citrate in Water for Injections. It also contains dextrose.

Sildenafil Citrate Injection contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of sildenafil, $C_{22}H_{30}N_6O_4S$.

Usual strength. 0.8 mg per ml.

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.

Tests

pH (2.4.24). 3.5 to 4.5.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. Equal volumes of *methanol* and *water*.

Buffer solution. Dissolve 3.5 g of *dipotassium hydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 7.0 with *dilute orthophosphoric acid* in *water*.

Test solution. Dilute a volume of the injection with *methanol* to obtain a solution containing 0.04 per cent w/v of Sildenafil.

Reference solution (a). A 0.046 per cent w/v solution of *sildenafil citrate IPRS* in *methanol*. Dilute 5.0 ml of the solution to 20.0 ml in the solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture.

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

Chromatographic system

–a stainless steel column 15 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5µm) (Such as Symmetry Shield RP-18),
– column temperature: 30°,
– mobile phase: A. a mixture of 14 volumes of *acetonitrile* and 86 volumes of the buffer solution,
B. a mixture of 74 volumes of *acetonitrile* and 26 volumes of the buffer solution,
– flow rate: 1 ml per minute,
– spectrophotometer set at 240 nm,
– injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	78	22
5	78	22
20	50	50
30	40	60
35	78	22
40	78	22

Name	Relative	Correction

	retention time	factor
Sildenafil N-oxide[1]	0.44	1.05
Sildenafil	1.0	---

[1]4-[(4-Ethoxy-3-(1-methyl-7-oxo-3-propyl-6,7-dihydro-1H-pyrazolo[4,3-d]pyrimidin-5-yl)phenyl)sulfonyl]-1-methylpiperazine 1-oxide.

Inject reference solution (a) and (b). The test is not valid unless the tailing factor is not more than 2.0 per cent, the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a) and the signal to noise ratio is not less than 10 in the chromatogram obtained with reference solution (b).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to sildenafil N-oxide is not more than 0.7 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent), the area of any other secondary peak is not more than 0.7 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 1.74 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). Ignore any peak with an area less than 0.35 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent).

Bacterial endotoxins (2.2.3). Complies with the test for bacterial endotoxins.

Sterility (2.2.11). Complies with the test for sterility.

Other tests. Comply with tests stated under Parenteral Preparations (Injection).

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a volume of the injection with the mobile phase to obtain a solution containing 0.008 per cent w/v of Sildenafil.

Reference solution. A 0.011 per cent w/v solution of *sildenafil citrate IPRS* in the mobile phase.

Chromatographic system
- –a stainless steel column 15 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5µm),
- – mobile phase: a mixture of 50 volumes of a buffer solution prepared by dissolving 15.4 g of *ammonium acetate* in 1000 ml of *water* and 50 volumes of *acetonitrile*,
- – flow rate: 1 ml per minute,
- – spectrophotometer set at 245 nm,
- – injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 per cent and the relative standard deviation for replicate injections is not more than 1.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{22}H_{30}N_6O_4S$ in the injection.

Storage. Preserve in single-dose glass containers and store at a temperature not exceeding 30°.

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