Fluconazole in Dextrose Injection

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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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Fluconazole in Dextrose Injection

Fluconazole in Dextrose Injection is a sterile solution containing Fluconazole and Dextrose. Fluconazole in Dextrose Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of fluconazole $C_{13}H_{12}F_2N_6O$.

Usual strengths. 2 mg per ml.

Identification.

A. 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).

B. To 5 per cent w/v solution, add 5 ml of hot *alkaline cupric-tartrate solution*; a red to orange precipitate of cuprous oxide is formed.

Tests

Related substances.

A. *For Nonpolar Impurities*. Determine by liquid chromatography (2.4.14).

Buffer solution. Dissolve 0.82 g of *anhydrous sodium acetate* in 1000 ml of *water*, adjusted to pH 5.0 with *1 M acetic acid*.

Solvent mixture. 20 volumes of *methanol* and 80 volumes of the buffer solution.

Test solution (a). Dilute a suitable volume of the injection with the solvent mixture to obtain a solution containing 0.1 per cent w/v of Fluconazole.

Test solution (b). Dilute 2.0 ml of test solution (a) to 10.0 ml with the solvent mixture.

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

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

Reference solution (c). A solution containing 0.00024 per cent w/v of *1,4-benzoquinone* and 0.002 per cent w/v of *fluconazole IPRS* in the solvent mixture.

Reference solution (d). A solution containing 0.004 per cent w/v, each of, *benzyl alcohol* and *fluconazole IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 10 cm × 4.0 mm, packed with octadecylsilane bonded to porous silica (3 µm) (such as Inertsil ODS-3),
- mobile phase: A. a mixture of 95 volumes of buffer solution and 5 volumes of *methanol*,
  B. a mixture of 60 volumes of *acetonitrile* and 40 volumes of *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 261 nm,
- injection volume: 100 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	77	23
5	77	23
30	40	60
43	77	23
50	77	23

Name	Relative retention time
1,4-benzoquinone	0.5
Fluconazole	1.0

Inject reference solution (b) and (c). The test is not valid unless the resolution between the peaks due to 1,4-benzoquinone and fluconazole is not less than 5.0, the tailing factor is not more than 1.5 for fluconazole peak, in the chromatogram obtained with reference solution (c) and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (b).

[NOTE—For the following calculations, do not include peaks eluting before fluconazole and do not include impurities at relative retention times of 2.00 to 2.12 and 3.14 to 3.26. The disregarded impurities at the specified relative retention times are process impurities monitored in the drug substance. Furthermore, disregard any peak due to an excipient or any peak not less than 0.02 per cent. This test is for determination of the late-eluting peaks, and hence the early-eluting peaks are not quantitated using this procedure.]

Inject reference solution (b) and test solution (a). In the chromatogram obtained with the test solution, the area of other secondary peak (nonpolar impurity) is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of areas of all the secondary peaks (nonpolar impurities) is not more than 2.5 times the area of principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent).

B. *For Polar Impurities*. Determine by liquid chromatography (2.4.14), as described under Related substances A (for nonpolar impurities) with the following modifications.

Chromatographic system

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	80	20
9	80	20
15	15	85
18	80	20
25	80	20

Name	Relative retention time
Hydroxymethylfurfural[1]	0.22–0.28
Aminofluconazole quaternary salt[2*]	0.3–0.36
Unidentified dextrose-related impurity	0.37–0.43
Fluconazole isomer[3*]	0.47–0.59
Fluconazole diol[4*]	0.68–0.74
Cyclohexanone[**]	0.77–0.83
Fluconazole	1.0

[*]Process impurity to include for information only. Not to be calculated and included in total degradation product.
[**]Potential impurity associated with drug product packaged in bags.
[1]5-Hydroxymethylfurfural.

[2]4-Amino-1-(2-(2,4-difluorophenyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl)-4*H*-1,2,4-triazolium bromide.
[3]2-(2,4-Difluorophenyl)-1-(1*H*-1,2,4-triazol-1-yl)-3-(4*H*-1,2,4-triazol-4-yl)propan-2-ol.
[4]2-(2,4-Difluorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)propane-1,2-diol.

The relative retention time with reference to benzyl alcohol for fluconazole is about 0.8.

Inject reference solution (b) and (d). The test is not valid unless the resolution between the peaks due to benzyl alcohol and fluconazole is not less than 1.8, the tailing factor is not more than 1.5 for fluconazole peak, in the chromatogram obtained with reference solution (d) and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (b).

Inject reference solution (b) and test solution (b). In the chromatogram obtained with test solution (b), the area of any other secondary peak (polar impurities) is not more than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of areas of all the secondary peaks (polar impurities) is not more than 0.5 times the area of principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent). Ignore any peak with an area less than 0.03 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.03 per cent).

The sum of the impurities (Nonpolar and polar Impurity) determined in Related substances A and B is not more than 1.0 per cent.

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

Bacterial endotoxins (2.2.3). Not more than 0.416 Endotoxin Unit per mg of fluconazole.

Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances B (For Polar Impurities) with following modifications.

Inject reference solution (a) and (d). The test is not valid unless the resolution between the peaks due to benzyl alcohol and fluconazole is not less than 1.8, the tailing factor is not more than 1.5 for fluconazole peak, in the chromatogram obtained with reference solution (d) and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and test solution (b).

Calculate the content of $C_{13}H_{12}F_2N_6O$ in the injection.

Storage. Store at a temperature not exceeding 30°.