Nicardipine 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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Nicardipine Injection

Nicardipine Hydrochloride Injection

Nicardipine Hydrochloride Injection is a sterile solution of Nicardipine Hydrochloride.

Nicardipine Hydrochloride Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of nicardipine hydrochloride, $C_{26}H_{29}N_3O_6$, HCl.

Usual strength. 2.5 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). 3.0 to 4.2.

Limit of *N*-Benzyl-*N*-Methyl-Ethanolamine. Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *acetonitrile* and 80 volumes of *water*.

Test solution. Dilute a volume of the injection containing 10 mg of Nicardipine Hydrochloride to 20.0 ml with the solvent mixture.

Reference solution. A 0.00025 per cent w/v solution of *N-benzyl-N-methyl-ethanolamine IPRS* (2-[benzyl(methyl) amino] ethanol) in 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 Inertsil ODS-3),
- column temperature: 30º,
- sample temperature:10°,
- mobile phase: A. a buffer solution prepared by dissolving 2.8 g of *sodium perchlorate monohydrate* in 1000 ml of *water*, adjusted to pH 2.5 with *perchloric acid*,
  B. a mixture of 50 volumes of *acetonitrile* and 50 volumes of *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 205 nm,
- injection volume: 50 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	95	5
10	82	18
12	20	80
22	20	80
24	95	5
32	95	5

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to *N*-benzyl-*N*-methyl-ethanolamine is not more than 4 times the area of the principal peak in the chromatogram obtained with the reference solution (2.0 per cent).

Content of Sorbitol *(if present)*. Not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of sorbitol $C_6H_{14}O_6$.

Determine by liquid chromatography (2.4.14).

NOTE—Prepare the solutions immediately before use.

Test solution. Mix the contents of not less than 3 injection vials to prepare a composite sample. Dilute a volume of the pooled sample containing 48 mg of sorbitol to 10.0 ml with the mobile phase.

Reference solution. A 0.48 per cent w/v solution of *sorbitol IPRS* (*D*-Glucitol) in the mobile phase.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with aminopropylsilane bonded to porous silica (5 µm) (such as Zorbax NH2),
- column temperature: 40º,
- mobile phase: a mixture of 30 volumes of a buffer solution prepared by dissolving 1 g of *tetrabutylammonium hydrogen sulphate* in 1000 ml of *water* and 70 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- refractive index detector maintained at 50º,
- injection volume: 25 µl.

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

Inject the reference solution and the test solution.

Calculate the content of sorbitol, $C_6H_{14}O_6$ in the injection.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE—Prepare the solutions immediately before use.

Test solution. Dilute a volume of the injection containing 20 mg of Nicardipine Hydrochloride in *methanol* and dilute to 10.0 ml with *methanol*.

Reference solution (a). A 0.002 per cent w/v solution of *nicardipine hydrochloride IPRS* in *methanol*.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml in *methanol*.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Inertsil ODS-2),
- column temperature: 50°,
- sample temperature:10°,
- mobile phase: A. a buffer solution prepared by dissolving 3.5 g of *sodium perchlorate monohydrate* in 1000 ml of *water*, add 1 ml of *triethylamine* and adjusted to pH 2.0 with *perchloric acid*,
  B. a mixture of 70 volumes of *acetonitrile* and 30 volumes of *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 239 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	70	30
15	70	30
55	35	65
60	35	65
62	70	30
70	70	30

Name	Relative retention time	Correction factor
Nicardipine mono acid[1]	0.72	---
Nicardipine impurity A[2]	0.94	2.38
Nicardipine	1.0	---

[1]5-(Methoxycarbonyl)-2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3-carboxylic acid,
[2]3-{2-[benzyl(methyl)amino]ethyl} 5-methyl 2,6-dimethyl-4-(3-nitrophenyl)pyridine-3,5-dicarboxylate oxalate.

Inject reference solution (a) and (b). The test is not valid unless the tailing factor is not more than 2.0, 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 nicardipine mono acid is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent), the area of any peak corresponding to nicardipine impurity A is not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (2.5 per cent), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent).

Total impurities, (sum of all the impurities determined in Related substances and *N*-benzyl-*N*-methyl-ethanolamine) is not more than 4.8 per cent.

Sterility (2.2.11). Complies with test for sterility.

Bacterial Endotoxins (2.2.3). Not more than 8.33 Endotoxin Unit per mg of nicardipine hydrochloride.

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

Assay. Determine by liquid chromatography (2.4.14).

NOTE—Prepare the solutions immediately before use.

Buffer solution. Dissolve 1.36 g of *monobasic potassium orthophosphate* in 1000 ml of *water*.

Solvent mixture. Equal volumes of buffer solution and *acetonitrile*.

Test solution. Dilute a volume of the injection containing 10 mg of Nicardipine Hydrochloride in the solvent mixture and dilute to 100.0 ml with the solvent mixture.

Reference solution. A 0.01 per cent w/v solution of *nicardipine hydrochloride IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Inertsil ODS-3V),
- column temperature: 40°,
- mobile phase: a mixture of 20 volumes of the buffer solution and 80 volumes of *methanol*,

– flow rate: 1 ml per minute,
– spectrophotometer set at 254 nm,
– injection volume: 20 µl.

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

Inject the reference solution and the test solution. Run the chromatogram 2 times the retention time of the principal peak.

Calculate the content of $C_{26}H_{29}N_3O_6$, HCl in the injection.

Storage. Store protected from light, in single dose glass vials at a temperature not exceeding 30°.

Labelling. Label it to indicate that it is to be diluted to the appropriate strength with a suitable intravenous fluid prior to administration.