METAPHARMACEUTICAL

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06/11/2025

Shilpa Pharma Lifesciences Limited

Unit-1: Plot No. 1A & 1A 'P', 1B, 2, 2A, 2B, 3A to 3E, 4A, 5A,
4B & 5B, Deosugur Industrial Area, Deosugur-584 170,
Raichur District, Karnataka State, India.
CIN: U24100KA2020PLC134081

CERTIFICATE OF ANALYSIS

Material Name	: NIFEDIPINE EP		
Batch No.	: NFDG250004	**Drug License No.**	: KTK/25/256/89
Source Batch No.	: NFD3250014	**Batch Quantity**	: 497.440 KG
Mfg. Date	: MAR-2025	**Dispatch Quantity**	: 10.000 KG
Retest Date	: FEB-2030	**A.R.No.**	: 40000123224

S.No.	Tests	Results	Specifications
1	Description<Ph. Eur 1.4>	Yellow crystalline powder	Yellow crystalline powder
2	Solubility<Ph. Eur 1.4>	Confirms	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol.
3	Identification		
3.1	Melting Range<Ph. Eur 2.2.14>	171.8°C to 173.1°C	Between 171°C to 175°C
3.2	By Infrared absorption spectrum	Confirms	The spectrum of Nifedipine should be concordant with the spectrum of Nifedipine standard.
3.3	By Thin-layer chromatography	Confirms	The principal spot in the chromatogram obtained with the test solution should be similar in position, appearance at 254 nm and size to the principal spot in the chromatogram obtained with the reference solution.
3.4	Colorimetry reaction Ph.Eur.	Confirms	An intense red colour develops which persists for not less than 5 minutes.
4	Impurity D and Other basic Impurities	0.3 mL/4g	Not more than 0.48 mL of 0.1 M perchloric acid (0.14%) should be required to change colour from brownish yellow to green.
5	Sulphated ash Ph. Eur 2.4.14	0.05%w/w	Not more than 0.1% w/w
6	Loss on Drying Ph.Eur 2.2.32	0.22%w/w	Not more than 0.5% w/w
7	Related substances (By HPLC) <Ph.Eur 2.2.29>		
7.1	Impurity A	0.01%w/w	Not more than 0.10 % w/w
7.2	Impurity B	Below LOD	Not more than 0.10 % w/w.
7.3	Any other Impurity	0.05%w/w	Not more than 0.10 % w/w.
7.4	Total Impurities	0.12%w/w	Not more than 0.30 % w/w.
8	Assay Ph.Eur 2.2.20	99.7%	Between 98.0% and 102.0% w/w (On dried basis)
9	Residual solvents (By GC) <IH>		
9.1	Methanol	Below LOQ	Not more than 2000 ppm
9.2	Iso propyl Alcohol	Not detected	Not more than 2000 ppm

Checked by :	Approved by :
Rajendra N 23.07.2025	Ramakrishna Reddy 23.07.2025

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S.No.	Tests	Results	Specifications
9.3	Acetic Acid By HPLC	Below LOQ	Not more than 1000 ppm

Storage Condition : Store at controlled room temperature (20°C to 25°C) protected from light and moisture.

Remarks : The material complies with the above respective specifications of EP/IH. *LOQ: Limit of Quantitation.*LOD : Limit of Detection

Checked by :	Approved by :
Rajendra N 23.07.2025	Ramakrishna Reddy 23.07.2025

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