



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	FELODIPINE USP	CAS No:	72509-76-3
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	Light yellow to yellow crystalline powder.	Light yellow crystalline powder.
2	Solubility	Freely soluble in Acetone and in methanol, very slightly soluble in heptane, insoluble in Water.	Complies
3	IDENTIFICATION - IR	The transmission minima (absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with the Felodipine working standard.	Complies
4	IDENTIFICATION - HPLC	The retention time of the major peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in Assay.	Complies
5	Residue on ignition	NMT 0.1%	0.06%
6	Loss on drying (at 105°C for 3 hours)	Not more than 0.5%	0.32%
7	Color of solution (20 mg/ml in methanol)	NMT 0.2 absorbance	Complies
8	Limit of ETHYL 3-AMINOCROTONATE	NMT 0.15%	Nil
9	Organic impurities by HPLC Methyl benzylidene acetoacetate	NMT 0.15%	Nil
10	Organic impurities by HPLC Felodipine related compound A	NMT 0.15%	Nil
11	Organic impurities by HPLC Sum of dimethyl felodipine and diethyl felodipine	NMT 1.0%	0.78%
12	Organic impurities by HPLC Any unspecified impurity	NMT 0.10%	0.06%
13	Organic impurities by HPLC Total impurities	NMT 0.15%	0.87%
14	Assay by HPLC (On Dried Basis)	NLT 98.0% and NMT 101.0%	100.3%
15	Residual solvent (Isopropyl Alcohol)	Not more than 5000 ppm	3200 ppm
16	Particle Size	D (90) Less than 10 µm	Complies

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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