



SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,

Aurangabad-431154, Maharashtra, India.

Tel: +91 8767062101 Email: enquiry@sdp.org.in

Website: www.sdp.org.in

CERTIFICATE OF ANALYSIS

Product Name	ALENDRONATE SODIUM USP	CAS No:	121268-17-5
Batch No.	2605001	Manufactured by	-Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity		Retest Date	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White, free-flowing powder.	White, free-flowing powder.
2	Solubility	Soluble in water, very slightly soluble in Dimethyl sulfoxide, in methyl alcohol, and in propylene glycol; practically insoluble in acetone, in acetonitrile, in alcohol, in chloroform, and in isopropyl alcohol.	Soluble in water, very slightly soluble in Dimethyl sulfoxide, in methyl alcohol, and in propylene glycol; practically insoluble in acetone, in acetonitrile, in alcohol, in chloroform, and in isopropyl alcohol.
3	Identification – By IR	IR of the sample should be concordant with that of standard	IR of the sample should be concordant with that of standard
4	Identification –Test for Sodium	It should give reaction for sodium.	Complies
5	Loss in Drying	16.1%-17.1%	16.35%
6	Organic impurities by HPLC Any individual impurity	Not more than 0.1%	Not detected
7	Organic impurities by HPLC Total impurities	Not more than 0.5%	Not detected
8	Assay By HPLC (On Dried Basis)	Not less than 98.0% and not more than 102.0%	99.80%

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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