

ADMAC LIFESCIENCES LIMITED

Plot No. 107A, 107-B & 108-D EPIP, Phase-I, Jharmajri, Baddi, Distt.-Solan (H.P.)



CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of product(Generic)	ZOLEDRONIC ACID INJECTION IP 4mg		
Name of product(Brand)	ZOLPROSIS 4		
Product Code	ALL/037A	A .R No.	AL/FG/L/26/017
Mfg. Date	JAN.2026	Generic Batch No.	ZDLA26A01
Exp. Date	DEC.2027	Generic Batch Size	8100 Vials
Specification No.	ALL/SP037A/01	Brand Batch No.	ZDLA26A01-B
STP No.	ALL/ST037A/01	Dispatch Qty.	2150 Vials
Date of sampling	20/01/2026	Date of Release	03/02/2026
Reference	IP&IHS	Page No.	Page 1 of 3

Sr. No.	Test	Specification	Results	Ref.
1.	Description (Visually)	White lyophilized cake in 10 ml clear moulded glass vial USP Type-I.	White lyophilized cake in 10 ml clear moulded glass vial USP Type-I.	IHS
2.	Identification A:HPLC	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.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponded to the peak in the chromatogram obtained with the reference solution.	IP
3.	Clarity of solution (Visually)	Solution of the drug should bear comparison with the standard	Solution of the drug is bear comparison with the standard	IHS
4.	Colour of solution (UV-Spectrophotometry)	Optical density (absorbance) of the test solution at 420 nm is NMT 0.05.	0.0058	IHS
5.	Dissolving Time	NMT 3 minutes	01 min 19 seconds	IHS
6.	pH (at 25±2°C)	4.5 to 7.0	6.47	IP
7.	Water(K.F.Titration)	NMT 7.0%	5.4312%	IHS

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Subhadrasan	Tejendra Kumar	Atul Saurawat
DESIGNATION	Officer	QC Analyst	Head QC
SIGN			
DATE	03/02/2026	03/02/2026	03/02/2026

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8.	Uniformity of dosage units(By weight variation)	L1- Maximum allowed acceptance value= L1=15.0 L2- Maximum allowed range for deviation of each dosage unit tested from the calculated value of M= L2= 25.0	6.20	IP
9.	Particulate matter (Liquid Particle counter)	Particles equal to or greater than 10 microns LT 6000/vial Particles equal to or greater than 25 microns LT 600/vial	1819 12	IP
10.	Assay (By HPLC) Each vial contains: Zoledronic acid eq. To Zoledronic acid anhydrous 4mg	NLT 3.6mg (90.0%) to NMT 4.4mg (110.0%)	4.1621mg (104.05 %)	IP
11.	Related substances (By HPLC) Single unidentified impurity Total impurities	NMT 1.0% NMT 2.0%	Not Detected Not Detected	IHS

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Subhadra Sen	T. Chandra Kumar	Atul Sanyal
DESIGNATION	Officer	QC Executive	Head QC
SIGN			
DATE	03/02/2026	03/02/2026	03/02/2026



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12.	Bacterial Endotoxins Test (Gel clot)	NMT 17.0 EU/mg of Zoledronic Acid	LT 17.0 EU/mg of Zoledronic Acid	IP
13.	Sterility (Membrane Filtration)	Must be sterile	Sterile	IHS

Remark: In the opinion of the undersigned the sample ~~Complies/Does not comply~~ with ~~IP/BP/USP/In~~ House specification

Detail of Examiner(s)/Approver:

Name: Atul Sarswat
Qualification: M. Tech (Biotechnology)
Reg. No./Enrollment No.: A0510709051
University Name: Amity University
Place: Noida (U.P)

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Rubhadasan	Jayashree Kumar	Atul Sarswat
DESIGNATION	Officer	QC Executive	Head QC
SIGN			
DATE	03/02/2026	03/02/2026	03/02/2026