

**ADMAC LIFESCIENCES LIMITED**



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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

<b>Name of product(Generic)</b>	ZOLEDRONIC ACID INJECTION IP 4mg		
<b>Name of product(Brand)</b>	ZOLPROSIS 4		
<b>Product Code</b>	ALL/037A	<b>A .R No.</b>	AL/FG/L/25/328
<b>Mfg. Date</b>	DEC.2025	<b>Generic Batch No.</b>	ZDLL25A18
<b>Exp. Date</b>	NOV2027	<b>Generic Batch Size</b>	8100 Vials
<b>Specification No.</b>	ALL/SP037A/01	<b>Brand Batch No.</b>	ZDLL25A18-G
<b>STP No.</b>	ALL/ST037A/01	<b>Dispatch Qty.</b>	1850 Vials
<b>Date of sampling</b>	26/12/2025	<b>Date of release</b>	09/01/2026
<b>Reference</b>	IP&IHS	<b>Page No.</b>	Page 1 of 2

Sr. No.	Test	Specification	Results	Ref.
1.	<b>Description (Visually)</b>	White lyophilized cake in 10 ml clear moulded glass vial USP Type-I.	White coloured lyophilized cake in 10 ml clear moulded glass vial USP Type-I.	IHS
2.	<b>Identification A:HPLC</b>	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.	<b>Clarity of solution (Visually)</b>	Solution of the drug should bear comparison with the standard	Solution of the drug bears comparison with the standard	IHS
4.	<b>Colour of solution (UV-Spectrophotometry)</b>	Optical density (absorbance) of the test solution at 420 nm is NMT 0.05.	0.0288	IHS
5.	<b>Dissolving Time</b>	NMT 3 minutes	01 min 29 seconds	IHS
6.	<b>pH (at 25±2°C)</b>	4.5 to 7.0	6.48	IP
7.	<b>Water(K.F.Titration)</b>	NMT 7.0%	2.0280%	IHS

	PREPARED BY	CHECKED BY	APPROVED BY
<b>NAME</b>	Ankit	Tahendhyanan	Atul Sausward
<b>DESIGNATION</b>	offices	QC Executive	Head QC
<b>SIGN</b>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
<b>DATE</b>	15/01/2026	15/01/2026	15/01/2026

ADMAC LIFESCIENCES LIMITED  
Corporate office: Admac House, SCO-84, Sec-5, Panchkula-134112 (India),

Format No.: F/QA/014/05-08

**ADMAC LIFESCIENCES LIMITED**

Plot No. 107A, 107-B &amp; 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/25/328
Mfg. Date	DEC.2025	Generic Batch No.	ZDLL25A18
Exp. Date	NOV2027	Generic Batch Size	8100 Vials
Specification No.	ALL/SP037A/01	Brand Batch No.	ZDLL25A18-G
STP No.	ALL/ST037A/01	Dispatch Qty.	1850 Vials
Date of sampling	26/12/2025	Date of release	09/01/2026
Reference	IP&IHS	Page No.	Page 2 of 2

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	8.38	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	878 14	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%)	4.186mg 104.65%)	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	Ankit	Tarundeep Kumar	Atul Sawhney
DESIGNATION	Offices	QC Executive	Head QC
SIGN			
DATE	15/1/2026	15/01/2026	15/01/2026

ADMAC LIFESCIENCES LIMITED  
Corporate office: Admac House, SCO-84, Sec-5, Panchkula-134112 (India),

Format No.: F/QA/014/05-08

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/25/328
Mfg. Date	DEC.2025	Generic Batch No.	ZDLL25A18
Exp. Date	NOV2027	Generic Batch Size	8100 Vials
Specification No.	ALL/SP037A/01	Brand Batch No.	ZDLL25A18-G
STP No.	ALL/ST037A/01	Dispatch Qty.	1850 Vials
Date of sampling	26/12/2025	Date of release	09/01/2026
Reference	IP&IHS	Page No.	Page 3 of 2

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	Ankit	Tehendra Kumar	Atul Sarswat
DESIGNATION	Officer	QC Engineer	Head QC
SIGN			
DATE	15/01/2026	15/01/2026	15/01/2026

ADMAC LIFESCIENCES LIMITED

Corporate office: Admac House, SCO-84, Sec-5, Panchkula-134112 (India),

Format No.: F/QA/014/05-08