

**ADMAC LIFESCIENCES**

107A &amp; 107B, EPIP, Phase-I, Jharmajri, Baddi, Distt.-Solan (H.P.) INDIA

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

<b>Name of product (Generic)</b>	METHOTREXATE INJECTION IP 50mg		
<b>Name of product(Brand)</b>	IMUXATE 50		
<b>Product Code</b>	ALI/018A	A .R No.	AL/FG/I/25/244
<b>Mfg. Date</b>	SEP.2025	Generic Batch No.	MTII25A06
<b>Exp.Date</b>	AUG.2027	Generic Batch Size	20200 Vials
<b>Specification No.</b>	ALI/SP018A/01	Brand Batch No.	MTII25A06-D
<b>STP No.</b>	ALI/ST018A/01	Dispatch Qty.	7320 Vials
<b>Date of sampling</b>	10/09/2025	Date of Release	25/09/2025
<b>Reference</b>	IP&IHS	Page No.	Page 1 of 2

<b>Sr. No.</b>	<b>Test</b>	<b>Specification</b>	<b>Results</b>	<b>Ref.</b>
1.	<b>Description</b>	A Clear, yellowish solution filled in 5 ml amber colour moulded glass vial USP Type I.	A Clear, yellowish solution filled in 5 ml amber colour moulded glass vial USP Type I.	IHS
2.	<b>Identification (By UV)</b>	Absorbance maxima shows at 258,303 and 371.	Absorbance maxima shows at 258,303 and 371.	IP
3.	<b>Clarity of solution</b>	Solution of the drug should bear comparison with standard.	Solution of the drug bears comparison with standard.	IHS
4.	<b>Colour of solution (By UV)</b>	The optical density should not exceed 0.08 at a wavelength of 425 nm.	0.0171	IHS
5.	<b>Average fill volume</b>	NLT 2.0 ml	2.00 ml	IHS
6.	<b>PH (at 25±2°C)</b>	7.5 to 9.0	8.02	IP
7.	<b>Particulate matter</b>	Particles equal to or greater than 10 microns LT 6000/vial Particles equal to or greater than 25 microns LT 600/vial	1133 7	IP
8.	<b>Assay (By HPLC) Each ml contains: Methotrexate IP 25 mg</b>	NLT 23.75 mg/ml (95.0%) to NMT 27.5 mg/ml (110.0%)	24.825 mg(99.30%)	IP

	<b>PREPARED BY</b>	<b>CHECKED BY</b>	<b>APPROVED BY</b>
<b>NAME</b>	Vikas Kumar	Chandana Kumar	Shalini
<b>DESIGNATION</b>	Executive	D. C. Executive	Head
<b>SIGN</b>			
<b>DATE</b>	30/09/2025	30/09/2025	30/09/2025

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<b>9.</b>	<b>Related substances (By HPLC)</b> Methotrexate impurity C Methotrexate impurity B Methotrexate impurity E Any other single impurity Total impurities	NMT 3.0% NMT 0.3% NMT 0.3% NMT 0.2% NMT 1.0%	Not Detected Not Detected Not Detected Not Detected Not Detected	IP
<b>10.</b>	<b>BET</b>	NMT 0.4 EU/mg of Methotrexate	LT 0.4 EU/mg of Methotrexate	IP
<b>11.</b>	<b>Sterility</b>	Must be sterile	Sterile	IP

**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:** Shashi Paul**Qualification:** M.Sc**Reg. No./Enrollment No.:** K51141232275**University Name:** Madhya Pradesh Bhoj University**Place:** Bhopal

	<b>PREPARED BY</b>	<b>CHECKED BY</b>	<b>APPROVED BY</b>
<b>NAME</b>	Vikas Kumar	Tapan Chakravarty	Shashi Paul
<b>DESIGNATION</b>	Executive	QC Analyst	Head
<b>SIGN</b>			
<b>DATE</b>	30/09/2025	30/09/2025	30/09/2025