



CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of product (Generic)	METHOTREXATE INJECTION IP 50mg		
Name of product(Brand)	IMUXATE 50		
Product Code	ALI/018A	A .R No.	AL/FG/I/25/235
Mfg. Date	AUG.2025	Generic Batch No.	MTIH25A05
Exp.Date	JUL.2027	Generic Batch Size	20200 Vials
Specification No.	ALI/SP018A/01	Brand Batch No.	MTIH25A05-G
STP No.	ALI/ST018A/01	Dispatch Qty.	2680 Vials
Date of sampling	28/08/2025	Date of Release	12/09/2025
Reference	IP&IHS	Page No.	Page 1 of 2

Sr. No.	Test	Specification	Results	Ref.
1.	Description	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.	Identification (By UV)	Absorbance maxima shows at 258,303 and 371.	Absorbance maxima shows at 258,303 and 371.	IP
3.	Clarity of solution	Solution of the drug should bear comparison with standard.	Solution of the drug bear comparison with standard.	IHS
4.	Colour of solution (By UV)	The optical density should not exceed 0.08 at a wavelength of 425 nm.	0.0263	IHS
5.	Average fill volume	NLT 2.0 ml	2.00 ml	IHS
6.	PH (at 25±2°C)	7.5 to 9.0	8.03	IP
7.	Particulate matter	Particles equal to or greater than 10 microns LT 6000/vial Particles equal to or greater than 25 microns LT 600/vial	44 1	IP
8.	Assay (By HPLC) Each ml contains: Methotrexate IP 25 mg	NLT 23.75 mg/ml (95.0%) to NMT 27.5 mg/ml (110.0%)	25.96 mg(103.82%)	IP

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Vikas Kumar	Tapan Kumar	Shankar
DESIGNATION	Executive	QC Executive	Head
SIGN			
DATE	30/08/2025	30/09/2025	30/09/2025



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9.	Related substances (By HPLC) 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%	0.038% Not Detected Not Detected BDL 0.038%	IP
10.	BET	NMT 0.4 EU/mg of Methotrexate	LT 0.4 EU/mg of Methotrexate	IP
11.	Sterility	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

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Vilkan Kumar	Jayashree Kumar	Shashi Paul
DESIGNATION	Executive	D. C. Executive	Head
SIGN			
DATE	30/09/2025	30/09/2025	30/09/2025