

M/S IVM PHARMACIA

Plot No. 05, Industrial Township, Bhatoli- Kalan, Baddi (H.P.) -173205 CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

	QUALITY CONTROL D	EPARTMENT	
PRODUCT NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	BATCH NO.	IK23324
GENERIC NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	A. R. NO.	QC/FP/23/1358
MFG. DATE	12/2023	PRODUCT CODE	K
EXP .DATE	11/2025	BATCH SIZE	1500 LTR
SAMPLE SIZE	27 X 100 ML	PACK SIZE	100 ML
DATE TEST STARTED	14/12/2023	DATE TEST COMPLETED	29/12/2023
MFG. LIC. NO.	LVP/18/09	SPECIFICATION NO.	FPS/F010-03

S.NO.	TEST OBSERVATION SPECIFICATION				
1	Description		SPECIFICATION		
2	Description	A clear colorless solution	A clear colorless solution.		
	Identification	Principle peak in assay solution is corresponds to principle peak in reference solution	In the assay, the principle peak in the chromatogram obtained with test solution corresponds to that in the chromatogram obtained with reference solution.		
3	p H .	6.19	4.5 to 6.5		
4	Light absorption	0.0043	The absorbance of infusion at 500 nm is not more than 0.04.		
5	Related Substances	0.001% ND 0.022%	4 Amino phenol		
6	Extractable volume	102 ml	Not less than nominal volume		
7	Bacterial Endotoxins Test	Less than 2.0EU/ml	. Not more than 2.0 EU/ml of Paracetamol		
8	Sterility	Sterile	No growth observed during incubation period of 14 days.		
9	Particulate Contamination	146.67 particles/container 6.67 particles/container	≥ 10 µm Not more than 6000 particles/ container. ≥ 25 µm Not more than 600 particles/ container.		
10	Assay Each 100ml contains: Paracetamol IP1000mg	1016.21 mg/100ml (101.6 %)	900.0mg to 1100.0mg/100 ml (90.0 % to 110.0 % of label claim)		
	Mannitol IP5.0%w/v	5.04 %w/v (100.8 %)	4.50 % w/v to 5.50 % w/v -(90.0 % to 110.0 % of label claim)		

Remark: The above sample complies / does not comply as per IH/ IP/BP/USP specification or external lab

analysis report. ND: Not Detected

	ANALYSED BY	CHECKED BY	APPROVED BY
Signature/ Date	Rakhi 2 29/12/23	Saul 23	J291123
	Officer-QC	Executive-QC	Quality Head
Format No : IV/M/OCC/03	M/E02 00		

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