

M/S IVM PHARMACIA

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

QUALITY CONTROL DEPARTMENT					
PRODUCT NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	BATCH NO.	IK24226		
GENERIC NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	A. R. NO.	QC/FP/24/0893		
MFG. DATE	06/2024	PRODUCT CODE	K		
EXP .DATE	05/2026	BATCH SIZE	1500 LTR		
SAMPLE SIZE	27 X 100 ML	PACK SIZE	100 ML		
DATE TEST STARTED	10/06/2024	DATE TEST COMPLETED			
MFG. LIC. NO.	LVP/18/09	SPECIFICATION NO.	FPS/F010-03		

S.NO.	TEST	OBSERVATION	SPECIFICATION	
1	Description	A clear colorless solution	A clear colorless solution.	
2	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	pH	6.18	4.5 to 6.5	
4	Light absorption	0.0011	The absorbance of infusion at 500 nm is not more than 0.04.	
5	Related Substances	0.012% 0.004 ppm 0.022%	4 Amino phenolNMT 0.1% 4 ChloroacetanilideNMT 10 ppm Any other secondary peaksNMT 0.25%	
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	Under test	No growth observed during incubation period of 14 days.	
9	Particulate Contamination	180.00 particles/container 53.33 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	1004.98 mg/100ml (100.5 %)	900.0mg to 1100.0mg/100 ml (90.0 % to 110.0 % of label claim)	
	Mannitol IP5.0%w/v	5.03 %w/v (100.7 %)	4.50 % w/v to 5.50 % w/v (\$0.0 % to 110.0 % of label claim)	

Remark: The above sample complies / dece net 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 24/06/24	24/06/24	\$224/06/24
Format No : IV/M/OCC/03	Officer-QC	Executive-QC	Quality Head

Format No.: IVM/QCC/024/F02-00

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