

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.	IK24207		
GENERIC NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	A. R. NO.	QC/FP/24/0851		
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	03/06/2024	DATE TEST COMPLETED	18/06/2024		
MFG. LIC. NO.	LVP/18/09	SPECIFICATION NO.	FPS/F010-03		

WIT G.	LIC. NO.	710/09	SP LOII ICATION NO.	
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	На	6.06	4.5 to 6.5	
4	Light absorption	0.0013	The absorbance of infusion at 500 nm is not more than 0.04.	
5	Related Substances	0.004% 0.004 ppm 0.023%	4 Amino phenol	
6	Extractable volume	102 ml	Not less than nominal volume	
7	Bacterial Endotoxins Tes	t 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	33.33 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	1028.15 mg/100ml (102.8 %)	900.0mg to 1100.0mg/100 ml (90.0 % to 110.0 % of label claim)	
	Mannitol IP5.0%w/v	1 (100 / %)	4.50 % w/v to 5.50 % w/v (90.0 % to 110.0 % of label claim) IP/BP/USP specification or external lab	

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

analysis report. ND: Not Detected'

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	ANALYSED BY	CHECKED BY	Al Tito
Signature/ Date	(Rakni	2018/06/24	18/06/124
Format No : IV/M/O 0 2 10	Officer-QC	Executive-QC	Quality Head

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

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