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.	IK24118
GENERIC NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	A. R. NO.	QC/FP/24/0497
MFG. DATE	03/2024	PRODUCT CODE	K
EXP .DATE	02/2026	BATCH SIZE	1500 LTR
SAMPLE SIZE	27 X 100 ML	PACK SIZE	100 ML
DATE TEST STARTED	01/04/2024	DATE TEST COMPLETED	15/04/2024
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	5.70	4.5 to 6.5
4	Light absorption	0.0016	The absorbance of infusion at 500 nm is not more than 0.04.
5	Related Substances	0.003% ND 0.026%	4 Amino phenol.....NMT 0.1% 4 Chloroacetanilide.....NMT 10 ppm Any other secondary peaks.....NMT 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	Sterile	No growth observed during incubation period of 14 days.
9	Particulate Contamination	86.67 particles/container Nil	≥ 10 µm Not more than 6000 particles/ container. ≥ 25 µm Not more than 600 particles/ container.
10	Assay Each 100ml contains: Paracetamol IP....1000mg Mannitol IP.....5.0%w/v	 1008.07 mg/100ml (100.8%) 5.05 %w/v (101.1 %)	 900.0mg to 1100.0mg/100 ml (90.0 % to 110.0 % of label claim) 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 14/04/24	14/04/24	15/04/24
	Officer-QC	Executive–QC	Quality Head