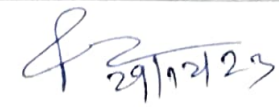# M/S IVM PHARMACIA

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.	IK23325
GENERIC NAME	PARACETAMOL INFUSION IP (1000 MG/100 ML)	A. R. NO.	QC/FP/23/1361
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	15/12/2023	DATE TEST COMPLETED	29/12/2023
MFG. LIC. NO.	LVP/18/09	SPECIFICATION NO.	FPS/F010-03

S.NO.	TEST	OBSERVATION	SPECIFICATION
1	Description	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	6.22	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	0.001% ND 0.022%	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	206.67 particles/container 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 IP....1000mg	1016.00 mg/100ml (101.6 %)	900.0mg to 1100.0mg/100 ml (90.0 % to 110.0 % of label claim)
	Mannitol IP.........5.0%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 29/12/23	Saul 29/12/23	29/12/23
	Officer-QC	Executive–QC	Quality Head