



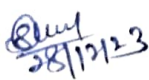
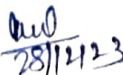

**M/S IVM PHARMACIA**  
Plot No. 05, Industrial Township,  
Bhatoli- Kalan, Baddi (H.P.) -173205  
**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

**QUALITY CONTROL DEPARTMENT**

PRODUCT NAME	PARACETAMOL INFUSION (1.0%w/v)	BATCH NO.	IK23322
GENERIC NAME	PARACETAMOL INFUSION (1.0%w/v)	A. R. NO.	QC/FP/23/1354
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	28/12/2023
MFG. LIC. NO.	LVP/18/09	SPECIFICATION NO.	FPS/F025-02

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	6.06	4.5 to 6.5
4	Light absorption	0.0021	The absorbance of infusion at 500 nm is not more than 0.04.
5	Related Substances	0.001% ND 0.018%	4 Amino phenol..... NMT 0.1% 4 Chloroacetanilide.....NMT 10 ppm Any other secondary peak.....NMT 0.25%
6	Extractable volume	102 ml	Not less than nominal volume
7	Bacterial Endotoxins Test	Less than 2.0 EU/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 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 BP....1000mg  Mannitol BP.....5.0%w/v	1006.19 mg/100ml (100.6%)  5.09 % w/v (101.8 %)	900.0 mg to 1100.0 mg/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 IP/ BP/USP specification or external lab analysis report. ND : Not Detected

	ANALYSED BY	CHECKED BY	APPROVED BY
Signature/ Date	 28/12/23	 28/12/23	 28/12/23
	Officer-QC	Executive-QC	Quality Head