





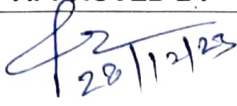
M/S IVM PHARMACIA
 Plot No. 05, Industrial Township,
 Bhatoli- Kalan, Baddi (H.P.) -173205
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

QUALITY CONTROL DEPARTMENT

| | | | |
|-------------------|---|---------------------|---------------|
| PRODUCT NAME | PARACETAMOL INFUSION IP (1000 MG/100 ML) | BATCH NO. | IK23323 |
| GENERIC NAME | PARACETAMOL INFUSION IP (1000 MG/100 ML) | A. R. NO. | QC/FP/23/1356 |
| 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/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 | 6.06 | 4.5 to 6.5 |
| 4 | Light absorption | 0.0041 | The absorbance of infusion at 500 nm is not more than 0.04. |
| 5 | Related Substances | 0.001% ND 0.023% | 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 | 53.33 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 IP....1000mg Mannitol IP.....5.0%w/v | 1003.71 mg/100ml (100.4 %) 5.02 %w/v (100.3 %) | 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 I/H/ 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 |