# 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.** | **IK24221** |
| **GENERIC NAME** | **PARACETAMOL INFUSION IP (1000 MG/100 ML)** | **A. R. NO.** | **QC/FP/24/0882** |
| **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** | **09/06/2024** | **DATE TEST COMPLETED** | **23/06/2024** |
| **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 | 6.19 | 4.5 to 6.5 |
| 4 | Light absorption | 0.0019 | The absorbance of infusion at 500 nm is not more than 0.04. |
| 5 | Related Substances | 0.009%<br>0.004 ppm<br>0.023% | 4 Amino phenol.....NMT 0.1%<br>4 Chloroacetanilide.....NMT 10 ppm<br>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 | 13.33 particles/container<br><br>Nil | ≥ 10 µm Not more than 6000 particles/ container.<br>≥ 25 µm Not more than 600 particles/ container. |
| 10 | Assay<br>Each 100ml contains:<br>Paracetamol IP....1000mg<br><br>Mannitol IP.....5.0%w/v | <br><br>1001.64 mg/100ml<br>(100.2 %)<br><br>5.03 %w/v<br>(100.7 %) | <br><br>900.0mg to 1100.0mg/100 ml<br>(90.0 % to 110.0 % of label claim)<br><br>4.50 % w/v to 5.50 % w/v<br>(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 23/06/24 | Saini 23/06/24 | 23/06/24 |
| | **Officer-QC** | **Executive–QC** | **Quality Head** |