




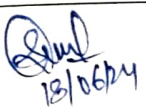
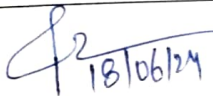
**M/S IVM PHARMACIA**  
Plot No. 05, Industrial Township,  
Bhatoli- Kalan, Baddi (H.P.) -173205  
**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

**QUALITY CONTROL DEPARTMENT**

|                   |   |                     |               |
|-------------------|---|---------------------|---------------|
| PRODUCT NAME      | PARACETAMOL INFUSION IP<br>(1000 MG/100 ML) | BATCH NO.           | IK24209       |
| GENERIC NAME      | PARACETAMOL INFUSION IP<br>(1000 MG/100 ML) | A. R. NO.           | QC/FP/24/0858 |
| 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 | 04/06/2024                                  | DATE TEST COMPLETED | ---           |
| 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   | 6.01  | 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%<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  | Under test  | No growth observed during incubation period of 14 days.  |
| 9     | Particulate Contamination  | 93.33 particles/container<br><br>Nil  | ≥ 10 µm Not more than 6000 particles/<br>container.<br>≥ 25 µm Not more than 600 particles/<br>container.  |
| 10    | Assay<br>Each 100ml contains:<br>Paracetamol IP....1000mg<br><br>Mannitol IP.....5.0%w/v | 1012.87 mg/100ml<br>(101.3 %)<br><br>5.01 %w/v<br>(100.2 %)                             | 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 IP/ BP/ USP specification or external lab analysis report. ND: Not Detected'

| Signature/ Date | ANALYSED BY   | CHECKED BY  | APPROVED BY   |
|-----------------|---|---|---|
|                 | <br>18/06/24 | <br>18/06/24 | <br>18/06/24 |
|                 | Officer-QC  | Executive-QC  | Quality Head  |