

M/S IVM PHARMACIA

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

| | QUALITY CO | NTROL DEPARTMENT | |
|-------------------|------------------------------------|---------------------|---------------|
| PRODUCT NAME | STERILE WATER FOR INJECTIONS IP | BATCH NO. | 10324001 |
| GENERIC NAME | STERILE WATER FOR INJECTIONS IP | A. R. NO. | QC/FP/24/0358 |
| MFG. DATE | 02/2024 | PRODUCT CODE | 03 |
| EXP .DATE | 01/2028 | BATCH SIZE | 1500 LTR |
| SAMPLE SIZE | 65 X 15 ML | PACK SIZE | 15 ML |
| DATE TEST STARTED | 05/03/2024 | DATE TEST COMPLETED | 20/03/2024 |
| MFG. LIC. NO. | MB/18/1020 | SPECIFICATION NO. | FPS/F014-04 |

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|-------|---------------------------|--|---|--|
| S.NO. | TEST | OBSERVATION | SPECIFICATION | |
| 1 | Description | Clear, colorless liquid, odorless | Clear, colorless liquid, odorless | |
| 2 | Appearance of solution | Clear practically free from suspended particles | Clear, colorless and practically free from suspended particles. | |
| 3 | рH | 5.59 | 5.0 to 7.0 | |
| 4 | Conductivity | 1.738 μs/cm | For container with a nominal volume of 10 ml or less, it the conductivity is not greater than 25μ S/cm, For container with a nominal volume of more than 10 ml, the conductivity is not greater than 5μ S/cm. | |
| 5 | Acidity or Alkalinity | Complies | Should meet the requirements | |
| 6 | Ammonium | Less than 0.6 ppm | Not more than 0.6 ppm | |
| 7 | Calcium & Magnesium | A pure blue color is produced | A pure blue color is produced | |
| 8 | Chlorides | Less than 0.5 ppm | Not more than 0.5ppm | |
| 9 | Nitrates | Less than 0.2 ppm | Not more than 0.2ppm | |
| 10 | Sulphates | Complies | The appearance of the solution does not change for at least 1 hour | |
| 11 | Oxidisable Substances | Complies | The pink colour of the solution does not disappear completely | |
| 12 | Residue on evaporation | 0.0010% | Not more than 0.004% for container 10 ml or less than 10ml | |
| 13 | Particulate contamination | 3.00 particles/container 1.00 particles/container | Not more than 0.003% for container more than 10ml $\geq 10 \ \mu m$ Not more than 6000 particles/ container $\geq 25 \ \mu m$ Not more than 600 particles/ container | |
| 14 | Extractable Volume | 15.5 ml | Not less than of nominal volume | |
| 15 | Bacterial Endotoxins | Less than 0.25 EU/ml | Not more than 0.25 EU/ml | |
| 16 | Sterility | Sterile | No growth observed during incubation period of 14 days. | |

Remark: The above sample complies / does not comply as per IH/ IP/BP/USP specification or external lab analysis report.

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|--------------------------------|--------------------|---------------------|--------------|
| Signature/ Date | (Rokhi 20103124 | (8 aug) 20103 24 | 20/03/24 |
| | Officer-QC | Executive-QC | Quality Head |
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