

|                               |   |                    |                   |
|-------------------------------|---|--------------------|-------------------|
| <b>Laboratory</b>             | <b>DKR Labs, Plot No. 121, IDA, Prashanthi Nagar, Kukatpally, Hyderabad, Andhra Pradesh</b> |                    |                   |
| <b>Accreditation Standard</b> | <b>ISO/IEC 17025: 2005</b>  |                    |                   |
| <b>Discipline</b>             | <b>Biological Testing</b>   | <b>Issue Date</b>  | <b>11.02.2014</b> |
| <b>Certificate Number</b>     | <b>T-2834</b>   | <b>Valid Until</b> | <b>10.02.2016</b> |
| <b>Last Amended on</b>        | <b>-</b>  | <b>Page</b>        | <b>1 of 1</b>     |

| <b>S.No.</b> | <b>Product / Material of Test</b> | <b>Specific Test Performed</b> | <b>Test Method Specification against which tests are performed</b> | <b>Range of Testing / Limits of Detection</b> |
|--------------|-----------------------------------|--------------------------------|--|---|
|--------------|-----------------------------------|--------------------------------|--|---|

## **I. DRUGS & PHARMACEUTICALS**

### **1. Drug Intermediates & Raw Materials**

|   |                               |                                  |                          |
|---|-------------------------------|----------------------------------|--------------------------|
| <b>a. Pharmaceutical Raw material and Formulations (Tablets, Capsules, Oral Suspensions, Pellets) General Tests</b> | Total aerobic microbial count | USP 2014, Page: 923 & 924 (1111) | ≥1_cfu /gm or ml         |
|   | Total yeast & moulds count    |                                  | ≥10 cfu/gm or ml         |
|   | <b>Pathogens:</b>             |                                  |                          |
|   | i) Escherichia coli           |                                  | Absent /Present /g or ml |
|   | ii) Staphylococcus aureus     |                                  | Absent /Present /g or ml |
|   | iii) Pseudomonas aeruginosa   |                                  | Absent /Present /g or ml |
|   | iv) Salmonella abony          |                                  | Absent /Present /g or ml |
| <b>2. Antibiotics</b>   |                               |                                  |                          |
| <b>a. Colistin Sulphate</b>   | Microbiology Assay            | STP No: DKR/STP/004-02           | 100 µg/mg to 1000 µg/mg  |

## **II. WATER**

|   |                               |                                 |                          |
|---|-------------------------------|---------------------------------|--------------------------|
| <b>1. Purified Water (Water for Medicinal Purpose )</b> | Total aerobic microbial count | USP 2014 Page: 925 & 926 (1112) | ≥1_cfu /gm or ml         |
|   | Total yeast &                 |                                 | ≥10 cfu/gm or ml         |
|   | <b>Pathogens:</b>             |                                 |                          |
|   | i) Escherichia coli           |                                 | Absent /Present /g or ml |
|   | ii) Staphylococcus aureus     |                                 | Absent /Present /g or ml |
|   | iii) Pseudomonas aeruginosa   |                                 | Absent /Present /g or ml |
|   | iv) Salmonella abony          |                                 | Absent /Present /g or ml |