



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Issuance of Data Sheet and Assignment of A.R. No. in Microbiology Laboratory	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 1. Purpose:** To lay down a procedure for Issuance of Data Sheet and Assignment of A.R. No. in Microbiology Laboratory.
- 2. Scope:** This Standard Operating Procedure is applicable at Microbiology section of Quality Control Department.
- 3. References & Annexures:**
  - 3.1 References:**
    - 3.1.1 In House.
  - 3.2 Annexures:**
    - 3.2.1 Annexure-1 : Inward record of Raw/Potable Water.
    - 3.2.2 Annexure-2 : Inward record of Purified Water.
    - 3.2.3 Annexure-3 : Inward and analysis record of Raw Materials.
    - 3.2.4 Annexure-4 : Inward and analysis record of Finished Good/Stability Samples.
    - 3.2.5 Annexure-5 : Inward and analysis record of Miscellaneous Samples.
    - 3.2.6 Annexure-6 : Microbiological Test Report.
    - 3.2.7 Annexure-7 : Data Issuance Record
- 4. Responsibilities:**
  - 4.1 Microbiologist / Executive - Quality control:**
    - 4.1.1 Responsible for the Issuance of Data Sheet and Assignment of A.R. No. in Microbiology laboratory.
    - 4.1.2 To maintain all the records as per SOP.
  - 4.2 Quality Assurance (QA) Department:**
    - 4.2.1 To check the SOP.
    - 4.2.2 To ensure implementation of SOP.
  - 4.3 Regulatory Affairs, Quality Head and Plant Head :**
    - 4.3.1 To review and approve new or revised SOP's.
- 5. Distribution:**
  - 5.1 QC
  - 5.2 QA



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### 6. Abbreviations and Definition of Terms:

#### 6.1 Abbreviations:

- 6.1.1 A.R. No. : Analytical Report Number
- 6.1.2 CC : Change Control
- 6.1.3 CFU : Colony forming unit
- 6.1.4 HOD : Head of Department
- 6.1.5 ml : Milliliter
- 6.1.6 NA : Not Applicable
- 6.1.7 QA : Quality Assurance
- 6.1.8 QC : Quality Control
- 6.1.9 SOP : Standard Operating Procedure

#### 6.2 Definition of Terms :

- 6.2.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations.

### 7. Procedure:

- 7.1 Section Head/Designee shall keep hard master copy of all documents in microbiology section.
- 7.2 Section Head/Designee shall maintain the track record of issued templates.
- 7.3 After receiving the sample from the respective section like Finished, Raw Material, Stability and Production, microbiologist shall enter the details of sample in Inward Record of Raw Water, Inward Record of Potable water, Inward Record of Purified Water, Inward and Analysis Record of Raw Materials, Inward and Analysis Record of Finished/Stability Samples and Inward and Analysis Record of Miscellaneous Samples as per Annexure-1, 2, 3, 4, and 5.
- 7.4 Microbiologist shall do the registration having separate Analytical Report Number of all samples in LIMS and take print/ photocopy of templates with all necessary details.
- 7.5 The analytical report number shall be numbered by eight characters.
- 7.6 The first two characters of A.R. No. shall be alphabets representing the nature of sample like 'FG' for Finished product and In process samples, 'RM' for Raw materials, 'SS' for stability Samples 'PW' for Purified Water, 'PT', for Potable Water, 'RW' for Raw water and 'MS' for miscellaneous samples.
- 7.7 The third and fourth character of analytical report no. shall denote the last two digits of year like 14 for 2014, 15 for 2015, 16 for 2016 and so on. The fifth, sixth, seventh and eight characters are numbers, which shall denote serial number of the requisition. The first analytical report number shall be 0001. The subsequent serial numbers shall be 0002, 0003, and so on.



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7.8 First sample of a product in year 2015 from January 2015 to December 2015 shall have analytical report number as

FG150001 for Finished and Inproces Samples.

RM150001 for Raw Material Samples.

SS150001 for Stability Samples.

PW150001 for Purified Water sample.

RW150001 for Raw Water sample.

PT150001 for Potable Water Samples.

MS150001 for Miscellaneous Samples.

7.9 Section Head/Designee microbiology shall issue the signed copy of document except LIMS generate document after signing in issuance register to the analyst after recorded the details as per Annexure-8.

7.10 Subsequently, the Section Head/Designee shall sign in the document in blue ink on the stamp in green color at right side corner of the template as a token of authorization of documents as per the provision where required.

**7.11 Reporting of Results:**

7.11.1 The analyst shall follow the respective SOP/STP/Specification for carrying out the analysis.

7.11.2 Results of Raw materials, Finished/Stability and Water samples shall be recorded in LIMS generated data sheet.

7.11.3 If the microbiological tests are not the part of LIMS generated data sheet then record the results on Annexure-6 (Microbiological Test Report) respectively.

7.11.4 Trend analysis shall be done quarterly by mentioning alert and action limits for all critical parameters like pH, conductivity, ROE and microbial counts and Total Organic Carbon for Purified water.















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**Annexure -6**

**MICROBIOLOGICAL TEST REPORT**

<b>Sample Name</b>		<b>Date of Sampling</b>	
<b>Batch Number</b>		<b>Date of Analysis</b>	
<b>A.R. Number</b>		<b>Date of Observation</b>	

S.No.	Test Parameter	Observation	Limit
1.	*Total Aerobic Microbial Count		NMT .....cfu/g or cfu/ml
2.	*Total Combined Molds and Yeasts Count		NMT .....cfu/g or cfu/ml
3.	<i>Escherichia coli</i>		Should be absent
4.	<i>Salmonella species</i>		Should be absent
5.	<i>Pseudomonas aeruginosa</i>		Should be absent
6.	<i>Staphylococcus aureus</i>		Should be absent
7.	*Enterobacteria		NMT .....cfu/g or cfu/ml

Positive Control:

Negative Control:

\* Limit of Total viable aerobic count and Enterobacteria shall be written as per specification.

**Remarks:** Sample Complies / Does not Comply with respect to above tests as per USP/IP/BP/EP Specification.

Microbiologist:

Checked By:

Date:

Date:

