



STANDARD OPERATING PROCEDURE

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

1.0 PURPOSE:

- 1.1 To lay down a procedure for Issuance of Data Sheet and Assignment of A.R. No. in Microbiology Laboratory.

2.0 SCOPE:

- 2.1 This Standard Operating Procedure is applicable in microbiology section at Quality Control department.

3.0 RESPONSIBILITY:

3.1 Microbiologist / Executive - Quality control.

- 3.1.1 Responsible for the Issuance of Data Sheet and Assignment of A.R. No. in Microbiology laboratory.

4.0 ACCOUNTABILITY:

- 4.1 Head – Quality Control/Designee -Ensure proper control and compliance of the SOP.

5.0 DEFINITION:

- 5.1 NA

6.0 PROCEDURE:

- 6.1 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/Filter/Soft 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, 5 and 6.

- 6.2 In charge Microbiology Laboratory shall issue data sheet for microbial limit test having separate Analytical Report Number.

- 6.3 The analytical report number shall be numbered by eight characters.

- 6.4 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 'PL' for Purified Water for Liquid section, 'PT' for Purified Water for Tab & Cap. Section, 'PO' for Purified Water for ointment section, 'TW', for Potable/filter/soft Water, 'RW' for Raw water and 'MS' for miscellaneous samples.



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- 6.5** The third and fourth character of analytical report no. shall denote the last two digits of year like 10 for 2010, 11 for 2011, 12 for 2012 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
- 6.6** First sample of a product in year 2012 from January 2012 to December 2012 shall have analytical report number as
- FG120001 for Finished and Inprocess Samples
 - RM120001 for Raw Material Samples
 - SS120001 for Stability Samples
 - PT120001 for Purified Water sample for Tab & Cap. Section
 - PL120001 for Purified Water sample for Liquid section
 - PO120001 for Purified Water sample for ointment section
 - TW120001 for Potable/filter/soft Water Samples
 - MS120001 for Miscellaneous Samples
- 6.7 Reporting of Results**
- 6.7.1 The analyst shall follow the respective GTP/STP or SOP for carrying out the analysis.
 - 6.7.2 Results of Raw materials, finished/stability, miscellaneous samples and different type of waters shall be recorded in Analytical data sheets as per Annexure- IX, Annexure-X, Annexure-XI and Annexure-XII.
 - 6.7.3 After completion of observation record the results as per respective Annexure on the main ADS of product available in the respective section.
 - 6.7.4 If the microbiological tests are not the part of main ADS then record the results on Annexure- VII and VIII (Microbiological Test Report) respectively for USP/IP and BP/Ph. Eur.
 - 6.7.5 Certificate of Analysis shall be issued as per Annexure-XIII.
 - 6.7.6 Trend analysis shall be done monthly, by mentioning alert and action limits for all critical parameters like pH, conductivity, microbial counts and Total Organic Carbon for Purified water.



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7.0 ANNEXURES:

- 7.1 Annexure-I : Inward record of Raw Water.
- 7.2 Annexure-II : Inward record of Potable/Filter/Soft water.
- 7.3 Annexure-III : Inward record of purified water.
- 7.4 Annexure-IV : Inward and analysis record of raw materials.
- 7.5 Annexure-V : Inward and analysis record of finished good/stability samples.
- 7.6 Annexure-VI : Inward and analysis record of miscellaneous samples.
- 7.7 Annexure-VII : Microbiological Test Report.
- 7.8 Annexure-VIII : Microbiological Test Report.
- 7.9 Annexure-IX : Data Sheet for Microbiological examination of non sterile products.
- 7.10 Annexure-X : Data Sheet for Microbiological Analysis of water.
- 7.11 Annexure-XI : Analytical Data Sheet for water.
- 7.12 Annexure-XII : Analytical Data Sheet for Purified water.
- 7.13 Annexure-XIII : Certificate of Analysis.

8.0 ABBREVIATIONS:

- 7.1 **SOP** : Standard Operating Procedure
- 7.2 **QC** : Quality Control
- 7.3 **GTP** : General Test Procedure
- 7.4 **No.** : Number
- 7.5 **NA** : Not Applicable
- 7.6 **CC** : Change Control
- 7.7 **HOD** : Head of Department
- 7.8 **A.R. No.** : Analytical Report Number
- 7.9 **ADS** : Analytical Data Sheet

9.0 REFERENCES:

- 9.1 Nil



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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10.0 REVISION HISTORY:

Revision No.	Effective date	Change Control Ref. No.	Description of change(s)