



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Analytical Report Numbering

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 2

1.0 OBJECTIVE:

1.1 To laydown the procedure for analytical report numbering.

2.0 SCOPE:

2.1 This SOP is applicable for analytical report numbering of Microbiology documents.

3.0 RESPONSIBILITY:

3.1 Microbiologist

4.0 ACCOUNTABILITY:

4.1 QC-Manager

5.0 PROCEDURE:

5.1 The purified water report the number consists of 12 characters e.g. PW/001/01/07. PW represents the type of sample, 001 indicates the report number, 01 indicates the month and 12 indicate the year.

5.2 For Water for Injection, Personnel monitoring, Nitrogen gas, Compressed air, Oxygen gas, the report number consists of 12 characters. All the characters are same as that of point No. 5.1 except the first two characters. The first two characters basing on the sample type is as follows

- 5.2.1 For Water for injection - WI
- 5.2.2 For Personnel monitoring – PM
- 5.2.3 For Nitrogen gas – NG
- 5.2.4 For Compressed air – CA
- 5.2.5 For Oxygen gas – OG

5.3 For Settle plate exposure, Air sampling, Surface monitoring, Sterility testing, BET, MLT and Bioburden the report number consists of 13 characters e.g. BET/001/01/07. BET represents the type of sample, 001 indicates the report number, 01 indicates the month and 12 indicate the year. The first three characters basing on the sample type are as follows

- 5.3.1 For settle plate exposure sterile area formulation – SSF
- 5.3.2 For air sampling sterile area formulation – ASF
- 5.3.3 For settle plate exposure non sterile area formulation – SNF
- 5.3.4 For settle plate exposure sterility testing area microbiology lab. – SSQ



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5.3.5 For air sampling sterility testing area microbiology lab. – ASQ

5.3.6 For settle plate exposure non sterile area microbiology lab. – SNQ

5.3.7 For air sampling non sterile area microbiology lab. – ANQ

5.3.8 For settle plate exposure stores area – SNS

5.3.9 For air sampling stores area – ANS

5.3.10 Sterility Test – SET

5.3.11 Bacterial endotoxin test – BET

5.3.12 Microbial limit test – MLT

5.4 For BET of Water for Injection the report number consists of 17 characters e.g. BET/WFI/001/01/07.

6.0 ABBREVIATIONS

6.1 BET Bacterial Endotoxin Test.

6.2 MLT Microbial Limit Test

6.3 SET Sterility Test

7.0 ANNEXURES

7.1 NIL.

CHANGE HISTORY

Supersedes SOP No.	Change Control No.	Changes made
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