



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Numbering System of Validation/Qualification	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE :

To describe a procedure for numbering system of Validation/Qualification documents related to Microbiology Section.

2.0 SCOPE :

This SOP is applicable to numbering system of Validation/Qualification documents allotted in Microbiology Section.

3.0 RESPONSIBILITY :

Officer, Executive – Quality Control
Head – Quality Control

4.0 PROCEDURE :

4.1 Numbering system of validation documents:

4.1.1 The numbering system followed for Validation of Microbial Limit Test Protocols shall be as follows:

PD/XXX/PMLT/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PMLT : Stands for Protocol for Microbial Limit Test.
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PMLT/01/00

4.1.2 The numbering system followed for Validation of Microbial Limit Test Reports shall be as follows:

PD/XXX/RMLT/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code



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RMLT : Stands for Report of Microbial Limit Test.

YY : Stands for serial number

ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RMLT/01/00

4.2 Numbering system of Disinfectant Efficacy Test Validation documents:

4.2.1 The numbering system followed for Validation of Disinfectant Efficacy Test Protocols shall be as follows:

PD/XXX/PDET/YY/ZZ

PD : Stands for Pharmadevils

XXX : Stands for Department code

PDET : Stands for Protocol of Disinfectant Efficacy Test

YY : Stands for serial number

ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PDET/01/00

4.2.2 The numbering system followed for Validation of Disinfectant Efficacy Test reports shall be as follows:

PD/XXX/RDET/YY/ZZ

PD : Stands for Pharmadevils

XXX : Stands for Department code

RDET : Stands for Report of Disinfectant Efficacy Test

YY : Stands for serial number

ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RDET/01/00

4.3 Numbering system of Antimicrobial Preservative Test documents:

4.3.1 The numbering system followed for Validation of Antimicrobial Preservative Test Protocols for Finished products shall be as follows:

PD/XXX/PAPT/YY/ZZ



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- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- AMPT : Stands for Protocol of Antimicrobial Preservative Test
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PAPT/01/00

4.3.2 The numbering system followed Validation of Antimicrobial Preservative Test Reports for Finished products shall be as follows::

PD/XXX/RAPT/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RAPT : Stands for Report of Antimicrobial Preservative Test
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RAPT/01/00

4.4 Numbering system of Media Hold Time Study documents:

4.4.1 The numbering system followed for Validation of Media Hold Time Study Protocols shall be as follows:

PD/XXX/PMHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PMHS : Stands for Protocol of Media Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PMHS/01/00

4.4.2 The numbering system followed for Validation of Media Hold Time Study Reports shall be as follows:

PD/XXX/RMHS/YY/ZZ



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- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RMHS : Stands for Reports of Media Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RMHS/01/00

4.5 Numbering system of Sterile Garment Hold Time Study documents:

4.5.1 The numbering system followed for Validation of Sterile Garment Hold Time Study

Protocols shall be as follows:

PD/XXX/PGHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PGHS : Stands for Protocol of Sterile Garment Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PGHS/01/00

4.5.1 The numbering system followed for Validation of Sterile Garment Hold Time Study Reports

shall be as follows:

PD/XXX/RGHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RGHS : Stands for Reports of Sterile Garment Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RGHS/01/00

4.6 Numbering system of Culture Suspension Hold Time Study documents:

4.6.1 The numbering system followed for Validation of Culture Suspension Hold Time Study



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Protocols shall be as follows:

PD/XXX/PCHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PCHS : Stands for Protocol of Culture Suspension Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PCHS/01/00

4.6.2 The numbering system followed for Validation of Culture Suspension Hold Time Study Report shall be as follows:

PD/XXX/RCHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RCHS: Stands for Reports of Culture Suspension Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RCHS/01/00

4.7 Numbering system of Fumigation Hold Time Study documents:

4.7.1 The numbering system followed for Validation of Fumigation Hold Time Study Protocols shall be as follows:

PD/XXX/PFHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PFHS : Stands for Protocol of Fumigation Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/PFHS/01/00



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4.7.2 The numbering system followed for Validation of Fumigation Hold Time Study Reports shall be as follows:

PD/XXX/RFHS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RFHS : Stands for Report of Fumigation Hold Time Study
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

Example : PD/QCM/RFHS/01/00

4.8 The numbering system followed for Validation of any miscellaneous Study Protocol shall be as follows:

PD/XXX/PMIS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- PMIS : Stands for the miscellaneous report
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

4.8.1 The numbering system followed for Validation of any miscellaneous Study Reports shall be as follows:

PD/XXX/RMIS/YY/ZZ

- PD : Stands for Pharmadevils
- XXX : Stands for Department code
- RMIS : Stands for the miscellaneous report
- YY : Stands for serial number
- ZZ : Stands for the version number starting from 00.

4.8.2 The numbering list of miscellaneous protocol shall be maintained as per respective



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list.

5.0 ANNEXURE (S):

Annexure-I : Template for Protocol (specific for microbiology section validation activity)

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

Nil

REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	----	New SOP	---



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ANNEXURE I

**TEMPLATE FOR PROTOCOL
(SPECIFIC FOR MICROBIOLOGY SECTION VALIDATION ACTIVITY)**

Title for Protocol

Protocol No.:

Page No.:

S.No.	ITEM DESCRIPTION
1.0	OVERVIEW
1.1	PROTOCOL APPROVAL
2.0	VALIDATION METHODOLOGY
3.0	ACCEPTANCE CRITERIA
4.0	SUMMARY
5.0	CONCLUSION
6.0	FINAL APPROVAL
7.0	ANNEXURE(S)