PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Protocol & Report Numbering System	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Protocol and Report Numbering System.

2.0 SCOPE:

This SOP is applicable for Codification of Protocol and Report Numbering System at …….

3.0 RESPONSIBILITY:

QA (Officer/Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP. Allotment of Protocol and Report numbering system.

QA (Manager): Training and effective implementation of this SOP to all concerned Departments

Respective Departments: Review and Checking of Numbering System of Protocols and Reports.

4.0 ACCOUNTABILITY:

Head QA: Approval, Ensure Training and Implementation of this SOP.

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE :

6.1 Precautions:

6.1.1 All the Protocol and Report shall be given unique number for its identification and Traceability.

6.1.2 Once Protocol and Report number is allotted to any protocol and report, the same number shall not be assigned to any other Protocol and Report.

6.1.3 Protocol and Report number shall be assigned by QA and same shall be recorded in respective protocol and report number issuance Log Book.

6.2 Department/Area Codes:

Following codes shall be used for Department/Area, wherever applicable in Protocol and Report Numbering:

S.No.	DEPARTMENT/AREA	CODE
1.	Quality Assurance	QA
2.	Quality Control	QC
3.	Engineering	EN
4.	Production (Three Piece Line)	TP
5.	Production (Dry Powder Line)	DP
6.	Production (Ampoule Line-1)	A1
7.	Production (Ampoule Line-2)	A2
8.	Production (Liquid Vial Line)	LV
9.	Production Common	PD
10.	Ware House (RM)	RM
11.	Ware House (PM)	PM
12.	Ware House (FG)	FG

Numbering System for User Requirement Specification:

DP/URS/XXX

DP **:** Decoding Pharma

/ **:** Separator

URS : User Requirement Specification

/ **:** Separator

XXX : Serial No. starts from 001, 002, 003…..etc.

6.3 NUMBERING SYSTEM FOR EQUIPMENT/INSTRUMENT/ HVAC QUALIFICATION PROTOCOL AND REPORT:

PC/XX/YY/WW/A/ZZZ

PC: Plant Code

/ : Indicates Separator

XX: Department Code

/ : Indicates Separator

YY: Equipment/Instrument Code (four digits for HVAC protocol & Report)

/ : Indicates Separator

WW: Indicates Qualification Document Code (DQ/IQ/OQ/PQ)

/ : Indicates Separator

A : P (For Protocol), R (For Report) & PR (For Protocol cum Report)

/ : Indicates Separator

ZZZ: Serial No. starts from 001, 002, 003…..etc.

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.4 NUMBERING SYSTEM FOR PROCESS OPTIMIZATION PROTOCOL AND REPORT:

Process Optimization Protocol and Report shall have a specific number as below:

PC/POP/XXXXXXXX

PC/POR/XXXXXXXX

PC : Plant Code

/ : Indicates Separator

POP : Indicates Process Optimization Protocol

POR : Indicates Process Optimization Report

/ : Indicates Separator

XXXXXXXX : Indicates Material Code. (Eight digits)

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.5 NUMBERING SYSTEM FOR PROCESS VALIDATION PROTOCOL AND REPORT:

Protocol Process Validation and Report shall bear a specific number as below:

PC/PVP/XXXXXXXX

PC/PVR/XXXXXXXX

PC : Plant Code

/ : Indicates Separator

PVP : Indicates Process Validation Protocol

PVR : Indicates Process Validation Report

/ : Indicates Separator

XXXXXXXX : Indicates Material Code. (Eight digits)

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.6 NUMBERING SYSTEM FOR CLEANING VALIDATION PROTOCOL AND REPORT:

PC/CVP/ZZ/XXX

PC/CVR/ZZ/XXX

PC : Plant Code

/ : Indicates Separator

CVP : Cleaning Validation Protocol

CVR : Cleaning Validation Report

/ : Indicates Separator

ZZ : Department Code

XXX : Serial Number start from 0001, 0002, 0003…etc

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.7 NUMBERING SYSTEM FOR ANALYTICAL METHOD VALIDATION PROTOCOL AND REPORT:

Analytical method validation protocol and report shall bear a specific number as below:

PC/AVP/XXXXXXXX/ZZ

PC/AVR/XXXXXXXX/ZZ

PC : Plant Code

/ : Indicates Separator

AVP : Indicates Analytical Method Validation Protocol

AVR: Indicates Analytical Method Validation Report

/ : Indicates Separator

XXXXXXXX : Indicates Material / Product Code (Eight digits)

/ : Indicates Separator

ZZ : Indicates Serial Number 01, 02, 03 … etc.

(For example if separate AVP of a Material / Product prepared for Assay, RS, Dissolution etc then01 shall be given for Assay, 02 shall be given for RS, 03 shall be given for Dissolution and so on.)

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.8 NUMBERING SYSTEM FOR STABILITY STUDY PROTOCOL AND REPORT:

Stability study protocol and report shall bear a specific number as below:

PC/SSP/ZZ/XXXXXXXX

PC/SSR/ZZ/XXXXXXXX

Where,

PC: Plant Code

/ : Indicates Separator

SSP : Stability Study Protocol

SSR : Stability Study Report

/ : Indicates Separator

ZZ : Indicates Department Code

/ : Indicates Separator

XXXXXXXX : Indicates Product Code (Eight digits)

Protocol and Report Number shall be shall be pre-printed in Header part of the document.

6.9 NUMBERING SYSTEM FOR FACILITY QUALIFICATION PROTOCOL & REPORT:

Numbering system for facility Qualification Protocol and Report shall be as below:

PC/XX/Y/NN

Where,

PC : Plant Code

/ : Indicates Separator

XX: Indicates Qualification Document Code (PQ)

/ : Indicates Separator

Y : Indicates (P for Protocol and R for Report)

/ : Indicates Separator

NN : Indicates Facility Code in which first digit represent Floor.

i.e. 00 represent Ground Floor.

01 represents First Floor.

02 represent Second Floor…..etc.

For Example:

The numbering for PQ Protocol of Ground Floor shall be as **PC/PQ/P/00.**

The numbering for PQ Report of First Floor shall be as **PC/PQ /P/01.**

Protocol and Report Number shall be pre-printed in header part of the document.

6.10 NUMBERING SYSTEM FOR TEMPERATURE MAPPING PROTOCOL AND REPORT:

A specific number is allotted for Temperature Mapping Protocol and Report:

PC/TMP/ZZ/NNN

PC/TMR/ZZ/NNN

Where,

PC: Plant Code

/ : Indicates Separator

TMP : Indicates Temperature Mapping Protocol

TMR : Indicates Temperature Mapping Report

/ : Indicates Separator

ZZ : Department Code

/ : Indicates Separator

NNN : Indicates Room /Equipment code - Number

or

ZNN : Z indicate Equipment code, NN- Equipment Last Number

Protocol and Report Number shall be pre-printed in header part of the document.

6.11 NUMBERING SYSTEM FOR MEDIA FILL VALIDATION PROTOCOL AND REPORT:

Media Fill protocol and report shall bear a specific number as below:

PC/XXXX/WW/A/ZZZ

PC/MFTP/PQ/P/001

Where,

PC: Plant Code

/: Indicates Separator

XXXX: Media Fill And last two XX Denoted line code

WW: Indicates Qualification Document Code (DQ/IQ/OQ/PQ)

/: Indicates Separator

A:P (For Protocol), R (For Report) &PR (For Protocol cum Report)

/: Indicates Separator

ZZZ: Indicates Protocol Number (001, 002, 003…..etc.)

For example: First Protocol of Media Fill for Ampoule line shall be numbered as PC/MFTP/PQ/P/001

Protocol and Report Number shall be pre-printed in header part of the document.

6.12 NUMBERING SYSTEM FOR HOLD TIME STUDY PROTOCOL AND REPORT (FOR PRODUCT):

Hold Time Study Protocol and report shall bear a specific number as below:

PC/HTP/ZZ/XXXXXXXX

PC/HTR/ZZ/XXXXXXXX

Where,

PC : Plant Code

/ : Indicates Separator

HTP : Indicates Hold Time Study Protocol

HTR : Indicates Hold Time Study Report

/ : Indicates Separator

ZZ : Indicates Department Code

/ : Indicates Separator

XXXXXXXX : Indicates Material /Product Code (Eight digits)

Protocol and Report Number shall be pre-printed in header part of the document.

6.13 NUMBERING SYSTEM FOR GENERAL VALIDATION PROTOCOL AND REPORT:

PC/GVP/NNN

PC/GVR/NNN

Where,

PC : Plant Code

/ : Indicates Separator

GVP : General Validation Protocol

GVR : General Validation Report

/ : Separator

NNN: Serial Number start from 001, 002, 003…etc

Protocol and Report Number shall be pre-printed in header part of the document.

6.14 NUMBERING SYSTEM FOR MICROBIAL LIMIT TEST VALIDATION PROTOCOL AND REPORT:

Microbial Limit Test Validation Protocol and Report shall bear a specific number as below:

PC/MVP/XXXXXXXX

PC/MVR/XXXXXXXX

Where,

PC : Plant Code

/ : Indicates Separator

MVP : Indicates Microbial Limit Test Validation Protocol

MVR : Indicates Microbial Limit Test Validation Report

/ : Indicates Separator

XXXXXXXX : Indicates Material / Product Code (Eight digits)

Protocol and Report Number shall be pre-printed in header part of the document.

6.15 NUMBERING SYSTEM FOR STERILITY TEST / METHOD VALIDATION PROTOCOL AND REPORT:

Sterility validation protocol and report shall bear a specific number as below:

PC/SVP/XXXXXXXX

PC/SVR/XXXXXXXX

Where,

PC : Plant Code

/ : Indicates Separator

SVP : Indicates Sterility Validation Protocol

SVR : Indicates Sterility Validation Report

/ : Indicates Separator

XXXXXXXX : Indicates Material / Product Code (Eight digits)

Protocol and Report Number shall be pre-printed in header part of the document

6.16 NUMBERING SYSTEM FOR BACTERIAL ENDOTOXIN TEST/ METHOD VALIDATION PROTOCOL AND REPORT:

Bacterial Endotoxin Test/ Method validation protocol and report shall bear a specific number as below:

PC/BVP/ XXXXXXXX

PC/BVR/ XXXXXXXX

Where,

PC : Plant Code

/ : Indicates Separator

BVP : Indicates Bacterial Endotoxin Test/ Method Validation Protocol

BVR : Indicates Bacterial Endotoxin Test/ Method Validation Report

/ : Indicates Separator

XXXXXXXX : Indicates Material / Product Code (Eight digits)

Protocol and Report Number shall be pre-printed in header part of the document.

6.17 NUMBERING SYSTEM FOR DISINFECTANTS EFFICACY TEST VALIDATION PROTOCOL AND REPORT:

Disinfectants Efficacy Test Validation protocol and report shall bear a specific number as below:

PC/DVP/ZZ/NNN

PC/DVR/ZZ/NNN

Where,

PC : Plant Code

/ : Indicates Separator

DVP : Indicates Disinfectants Efficacy Test Validation Protocol

DVR : Indicates Disinfectants Efficacy Test Validation Report

/ : Indicates Separator

ZZ : Indicates Department Code

/ : Indicates Separator

NNN : Indicates Protocol Serial Number (001, 002, 003 … etc.)

Protocol and Report Number shall be pre-printed in header part of the document.

6.18 NUMBERING SYSTEM FOR HOLD TIME STUDY PROTOCOL AND REPORT:

Sterilized Equipments, Sterilized rubber bung, Sterilized Flip of seal, Sterilized Garments and Cleaned Equipments. Hold Time Study Protocol and report shall bear a specific number as below:

PC/HTSP/ZZ/XXX/NNNN

PC/HTSR/ZZ/XXX/NNNN

Where,

PC : Plant Code

/ : Indicates Separator

HTSP : Indicates Hold Time Study Protocol

HTSR : Indicates Hold Time Study Report

/ : Indicates Separator

ZZ : Indicates Department Code

/ : Indicates Separator

XXX : Indicates the Article Code as follows:

SEQ – Sterilized Equipments **SRB** – Sterilized Rubber Bung

SFP – Sterilized Flip of seal **SGM**-Sterilized Garments

CEQ-Cleaned Equipments

/ : Indicates Separator

NNNN : Indicates Protocol Serial Number (001, 002, 003 …etc

Protocol and Report Number shall be pre-printed in header part of the document.

6.19 NUMBERING SYSTEM FOR RE-QUALIFICATION REPORT:

Numbering system for Re-Qualification Report shall be as below:

PC/XX/YY/WWW/A/ZZZ

PC : Plant Code

/ : Indicates Separator

XX : Department Code

/ : Indicates Separator

YY : Equipment / Instrument Code(four digits for HVAC protocol & report)

/ : Indicates Separator

WWW: Indicates Qualification Document Code (RPQ)

/ : Indicates Separator

A : P(For Protocol), R(For Report) & PR(For Protocol Cum Report)

/ : Indicates Separator

ZZZ : Serial No. starts from 001, 002, 003…..etc.

Re- Qualification Protocol and Report Number shall be shall be pre-printed in Header part of the document.

7.0 ABBREVIATIONS:

Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
URS	User Requirement Specification
HVAC	Heating Ventilation & Air Conditioning
DQ	Design Qualification

IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
URS	User Requirement Specification
HVAC	Heating Ventilation & Air Conditioning

8.0 ANNEXURES:

Not Applicable

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department.
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Engineering Department.
- Controlled Copy No. 05 Warehouse Department.

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		