



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Numbering of validation/Qualification documents, equipments /Instruments BMR/BPR	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for numbering system of standardization, Numbering of validation/Qualification documents, equipments/Instruments, BMR/BPR.

2.0 SCOPE:

This is SOP applicable to numbering system allotted in

3.0 RESPONSIBILITY:

Officer, Executive – Quality Assurance

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Numbering system of Standardization documents :

5.1.1 The numbering system followed for all the standardization protocols shall be as

Follows:

PPS/XX/YY

P : Stands for concern protocol

PS : Stands for Process Standardization.

XX : Stands for product code

YY : Stands for the version number starting from 00.

Example: PPS/AB/00

AB: Product code no. of (A) mg and (B) mg Tablet.

5.2 Numbering system of Process Validation documents:

5.2.1 The numbering system followed for all the validation, protocols shall be as follows:

PPV/XX/YY

P : Stands for concern protocol



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PV : Stands for Process Validation

XX : Stands for product code

YY : Stands for the version number starting from 00.

Example: PPV/AB/00

AB: Product code no. of (A) mg and (B) mg Tablet

5.3 Numbering System of qualification protocols of equipment/system:

5.3.1 The numbering system followed for all the qualification, protocols shall be as follows:

For Protocol Reference No.:-

..../N1/PZZ/XXX/00

Where-

.....: Stands for

N1 : Stands for New Delhi (Block-1)

P : Stands for Protocol

ZZ : Stands for IQ, OQ & PQ

XXX: Stands for Identity of equipment

00 : Stands for Version Number

For Protocol Report No.:-

PSL/N1/RZZ/XXX/00

Where-

.....: Stands for

N1 : Stands for New Delhi

R : Stands for Report

ZZ : Stands for IQ, OQ & PQ

XXX : Stands for Identity of equipment

00: Stands for Version Number

For example: Generic protocol of Installation Qualification, prepared by QA department, for equipment identity and version number for first issue will be as follows:

PSL/N1/PIQ/RMG/00 & PSL/N1/RIQ/RMG/00



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Note: In case of more than one equipment/system of same equipment/ system Identity, the equipment/ system identity number shall be sequence numbered as AHU01, AHU02, CMP1, CMP2 and so as.

For Example: **PSL/N1/PIQ/CMP1/00 & PSL/N1/RIQ/CMP2/00**

PSL/N1/PIQ/AHU01/00 & PSL/N1/RIQ/ AHU01/00

5.3.2 Changes (if any) in the version number shall be incorporated as and when Re-qualification required which shall be approved by QA.

5.4 Numbering System of Equipment/System Identification Number:

EQI/XXX/YY

Where-

EQI: Stands for Equipment Identification

XXX: Stands for Identity of equipment

YY: Stands for Serial Number

For example: EQI/RMG/01

Note: For AHU System identification number to be given as per DQ

e.g. AHU No. : AHU-AG1

5.5 Numbering System of re-qualification protocols of equipment/system: 5.5.1 The numbering system followed for all the re-qualification protocols shall be as follows:

PSL/N1/PZZ/XXX/00

.....: Stands for

N1 : Stands for New Delhi

P : Stands for Protocol

ZZ : Stands for RQ,

XXX: Stands for Identity of equipment

00 : Stands for Version Number

For example: Generic protocol of re-qualification, prepared by QA department, for equipment identity and version number for first issue will be as follows:

PSL/N1/PRQ/RMG/00



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5.6 Numbering System of re-qualification reports of equipment/system:

5.6.1 The numbering system followed for all the validation, reports shall be as

PSL/N1/RZZ/XXX/00

Where-

.....: Stands for

N1 : Stands for New Delhi

R : Stands for Report

ZZ : Stands for RQ

XXX : Stands for Identity of equipment

00 : Stands for Version Number

For example Generic protocol of re-qualification, prepared by QA department, for equipment identity and version number for first issue will be as follows:

PSL/N1/RRQ/RMG/00

5.7 Numbering System of PLC/BMS validation protocols:

5.7.1 The numbering system followed for all the validation protocols for PLC/ BMS shall be as follows:

PSL/N1/ABC/YYY/ZZ

.....: Stands for

N1: Stands for New Delhi

A : Stands for concerned protocol (P)

BC : Stands for qualification (IQ/OQ)

YYY: Stands for Equipment identity (PLC/BMS)

ZZ : Stands for the version number starting from 00.

For example: Generic protocol of PLC validation, prepared by QA department, version number for first issue will be as follows:

MPL/N1/PIQ/PLC/00

5.8 Numbering System of PLC/BMS validation reports:

5.8.1 The numbering system followed for all the validation, reports shall be as follows:

PSL/N1/ABC/YYY/ZZ



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.....: Stands for

N1 : Stands for New Delhi

A : Stands for concerned protocol (P)

BC : Stands for qualification (IQ/OQ)

YYY : Stands for Equipment identity (PLC/BMS)

ZZ : Stands for the version number starting from 00.

For example: Generic protocol of PLC validation, prepared by QA department, version number for first issue will be as follows:

PSL/N1/RIQ/PLC/00

5.9 Numbering system for the equipments/instruments for QC. Department:

5.9.1 The equipment /instruments list shall be prepared by concerned department. 5.9.2

The numbering of the equipments/instruments shall be as follows:

EQ/XXX/YY/ZZ

EQ : Stands for Equipment/Instrument

XXX : Stands for the department code

YY : Stands for equipment identity

ZZ : Stands for Serial Number of equipment/ instrument

For Example: EQ/QCD/PH/01

5.9.3 The serial number shall be assigned by the QA department mentioning the details of the equipment.

5.10 Numbering system of the BMR/BPR:

5.10.1 The BMR/BPR list shall be prepared by QA department.

5.10.2 The numbering of the BMR/BPR shall be as follows:

PSL/XXX/YYYY/XX/00

.....: Stands for

XXX : Stands for department code

YYY : Stands for the BMR/BPR

XX : Stands for Product code

00 : Stands for first version

For Example: PSL/PRD/BMR/OB/00 and PSL/PRD/BPR/OB/00.



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5.10.3 The number shall be assigned by the QA department mentioning the details of the BMR/BPR.

5.10.4 Changes (if any) in the version number shall be incorporated as and when revision shall be done and approved by QA.

5.10.5 Department code shall be as per SOP No.: QAD/001.

5.10.6 Incase of different batch size of same product, the BMR number shall be sequence numbered as BMR, BMR1, BMR2 and so as.

For Example: PSL/PRD/BMR1/OB/00, PSL/PRD/BMR2/OB/00.

5.10.6 Incase of same BMR, but different pack style (BPR), the BPR number shall be sequence numbered as BPR, BPR1, BPR2 and so as.

For Example: PSL/PRD/BPR1/OB/00, PSL/PRD/BPR2/OB/00.

5.11 Numbering system of miscellaneous validation:

5.11.1 The numbering of validation protocol for miscellaneous system/procedure shall be as follows:

PSL/XXX/MIS/YYYY/ZZ

.....: Stands for

XXX : Stands for department code

MIS : Stands for the miscellaneous

YYY : Stands for miscellaneous item

ZZ : Stands for the version number starting from 00.

5.12 Numbering system for Site master file:

5.12.1 The numbering of Site master file shall be as follows

PSL/N1/SMF1/ZZ

.....: Stands for

N1: Stands for New Delhi

SMF1: Site master file (Block -1)

ZZ: revision number

5.13 Numbering system for Validation Master Plan:

MPL/N1/QAD/VMP1/ZZ

.....: Stands for

N1 : Stands for New Delhi



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QAD: Quality Assurance department
VMP1: Validation master plan (Block -1)
YY : revision number

5.14 Numbering system for Validation Policy:

PSL/N1/QAD/VP1/ZZ

.....: Stands for

N1: Stands for New Delhi

QAD: Quality Assurance department

VP: Validation policy

YY: revision number

6.0 ABBREVIATION(S):

Nil

7.0 REFERENCES:

NA

8.0 ANNEXURES:

Annexure: I Equipment/Instrument Identity code

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION