1. **PURPOSE:**

To lay down the procedure for numbering system to various documents.

1. **SCOPE:**

This procedure is applicable for assigning numbering system to various documents in Discovery Laboratories Pvt. Ltd.

1. **RESPONSIBILITY:**
   1. It is the responsibility of QA personnel to assign the numbering system.
   2. It is the responsibility of the respective departments to follow the numbering system.
   3. Head-QA/ Designee approve and implementation of the procedure.
2. **DEFINATIONS:**

Nill

1. **PROCEDURE:**

The following numbering system shall be followed for various documents.

* 1. Temperature mapping documents:

For Protocol:

TM/PC/YYNNN

Here,

TM : Temperature mapping documents

PC : Protocol

YY : Year of the protocol prepared

NNN : serial number starts with 001 in a year

e.g.: TM/PC/18001

For Report:

TM/R/YYNNN

Here,

TM : Temperature mapping documents

R : Report

YY : Year of the report prepared

NNN : serial number starts with 001 in a year

e.g.: TM/R/18001

* 1. Analytical method verification documents:

For Protocol:

MV/PC/XXX/YYNNN

Here,

MV : Method verification document

PC : Protocol

XXX : Product code along with stage number

YY : Year code

NNN : Serial Number

e.g.: MV/PC/Z3/18001

For Report:

MV/R/XXX/YYNNN

Here,

MV : Method verification document

R : Report

XXX : Product code along with stage number

YY : Year code

NNN : Serial Number

e.g.: MV/R/Z3/18001

* 1. Equipment Re-Qualification documents:

QLPR/AA-BBB/VV

Here,

QLPR : Equipment Re-qualification document

AA-BBB : Equipment type and ID Number

VV : number of times re-qualification performed, starts with 01, 02, …..

e.g.: QLPR/RV-001/01

* 1. General Protocol and Reports:

For Protocol:

GEN/PC/YYNNN

Here,

GEN : General document

PC : Protocol

YY : Year code

NNN : Serial number

e.g.: GEN/PC/18001

For Report:

GEN/R/YYNNN

Here,

GEN : General document

R : Report

YY : Year code

NNN : Serial number

e.g.: GEN/R/18001

* 1. PCO BPR (Product wise, if any):

ECR/XXX/EQ/NNN-VV

Here,

ECR : Equipment cleaning record

XXX : Product code

EQ : Equipment type

NNN : Serial number in the equipment

VV : Revision number

e.g.: ECR/PNB/RV/001-00

* 1. Water system Qualification documents:

For Protocol:

GEN/PC/WS/YYNNN

Here,

GEN : General document

PC : Protocol

WS : Water system

YY : Year code

NNN : Serial number

e.g.: GEN/PC/WS/17001

For Report:

GEN/R/WS/YYNNN

Here,

GEN : General document

R : Report

WS : Water system

YY : Year code

NNN : Serial number

e.g.: GEN/R/WS/18001

1. **FORMATS/ ANNEXURE(S):**

Nill

1. **CHANGE HISTORY:**

| **Revision No.** | **Effective Date** | **Details of Revision** | **Ref CCF No.** |
| --- | --- | --- | --- |
| 00 |  | New SOP is introduced | CCF/GEN/18007 |