PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Control of Master Data Generation by Computer System	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for control over the Master Data Generated by Computer System

2.0 SCOPE

This SOP is applicable for all Master Data Generated from computer for Quality Control department .

3.0 RESPONSIBILITY – Execution – Executive QC.
Checking - Assistant Manager QC.

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE

5.1 STPs, Data sheets, SOPs, GTPs, COAs, Validation & stability report etc. shall be generated in computer by concerned personnel in QC department.

5.2 On finalisation, concerned personnel shall take the print outs of document generated on computer and same shall be checked by Manager QC & thereafter, QC shall forward the checked and signed document to QA for further action.

5.3 After receipt of controlled and approved copy of STPs, GTPs, SOPs, Data sheets etc from QA department, the concerned personnel from QC and IT department shall arrange to protect the soft copy of these documents (generated on computer) by giving permission of "READ ONLY" to QC personnel. If required, make it password protected with due permission of Manager QC.

5.4 Taking printout of any document generated on computer of QC Department after approval is permitted.

5.5 Concerned personnel from QC department, looking after document control shall prepare index in computer for specifications and STPs, GTPs, SOPs, and Data sheets etc. for easy traceability and for index updation on receipt of new or superseded documents from QA.

5.6 Take printouts of all Index and place at the beginning of respective file.

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

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7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

A.R. No.: Analytical report number

RM : Raw Material

Sr. No. : Serial number

Qty. : Quantity

Sign. : Signature

STPs : Standard Test Procedures

GTPs : General Test Procedures

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Annexure-I : Index for Data Sheet of RM/PM/FP/STABILITY

Annexure-II : Index for STPs of RM/PM/FP

Annexure-III : Index of GTPs (IP, BP, USP)

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ANNEXURE-I

INDEX FOR DATA SHEET OF RM/PM/FP/STABILITY

S.No.	Name of Product	Reference	Effective Date	Revision No.	Supercede Date	Remark

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ANNEXURE-II

INDEX FOR STPS OF RM/PM/FP

S.No.	Name of Raw Material	Reference	Effective Date	Revision No.	Supercede Date	Remark

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ANNEXURE-III

INDEX OF GTPS OF IP, BP, USP

S.No.	Title of GTP	GTP No.	Reference	Effective Date	Revision No.	Remark