PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation , Approval, Distribution, Revision and Destruction of Analytical Data Sheet	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Preparation, Approval, Distribution, Revision and Destruction of Analytical Data Sheet.

2.0 SCOPE:

This SOP is applicable for Preparation, Approval, Distribution, Revision and Destruction of Analytical Data Sheet. in the Quality Control Department.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Analytical Data sheet for each RM/FG/PM will be prepared by QC officer. It will be check by second QC officer or Executive.

5.2 Each materials (Raw , Packing and Finished product) shall have a unique Analytical raw data sheet number which shall be prepared by the QC personal in the format as per Annexure –I

5.3 For Raw Materials & Packaging materials:

5.3.1 All analytical data sheet raw materials and packaging materials shall have ten characters.

e.g. For Raw material

RM	/	0001	-	00

RM Raw Materials

/ Slash

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0001 Code number of the materials / Products

\- Dash

00 Last two digit are revision number,

		/					-		

_____ _____ _____

RM Code No. Revision

5.3.2 The first two digits represent Materials / Products referring to specification or standards test procedures respectively.

5.3.3 The third digit is a slash "/"

5.3.4 The fourth to sixth digit represents the code no of the material.

5.3.5 The seven digit is a "-"

5.3.6 The eight and ninth digits represents the revision no. which shall be start with "00" for the version followed by sequential numbers fot each subsequent revision.

e.g. For Packaging materials

PM	/	0001	-	00

PM Packing Materials

/ Slash

0001 Code No of the Materials / Products.

\- Dash

00 Last two digit are revision , represented as:

		/					-		

_____	_____	_____
PM	Code No.	Revision

5.4 For Finished product Tablets, Capsules, & Inprocess sample:

5.4.1 All analytical Data sheet for finished product tablets and finished product capsules shall have ten characters.

e.g. For Finished product Tablets

FP	/	0001	-	00

FP Finished product Tablets

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____	_____	_____
FM	Code No.	Revision

e.g. For Finished product capsules

FC	/	0001	-	00

FC Finished product Capsule

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

FC Code No. Revision

5.4.2 AR Number for Inprocess sample report will consist of 10 characters.

e.g. For Inprocess Sample

IP	/	0001	-	00

IP Inprocess Sample

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

IP Code No. Revision

5.5 For Validation Samples:

5.5.1 All analytical Data sheets for validation samples shall have 11 characters.

e.g. For Validation sample

VAL	/	0001	-	00

VAL Validation sample

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

VAL Code No. Revision

5.6 For Raw water , Purified water & swab sample:

5.6.1 All analytical Data Sheet for Raw Water, Purified Water & swab sample shall have 10 characters.

e.g. For Raw water sample

RW	/	0001	-	00

RW Raw water sample

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

RW Code No. Revision

e.g. For Purified water sample.

PW	/	0001	-	00

PW Purified water sample

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

PW Code No. Revision

e.g. For swab samples (Wash water)

SW	/	0001	-	00

SW Swab water sample

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

SW Code No. Revision

5.7 For Pre shipment or Free sample:

5.7.1 All analytical Data Sheet for pre shipment or free sample shall have 10 characters.

e.g.

PS	/	0001	-	00

PS Preshipment or free samples

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

PS Code No. Revision

5.8 For Trial Batches:

5.8.1 All analytical Data Sheet for trial batches shall have 10 characters.

e.g.

TR	/	0001	-	00

TR Trial batches samples

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

		/					-		

_____ _____ _____

TR Code No. Revision

5.9 All analytical Data sheet for microbial test shall have been eleven characters. Analytical report for microbiological section shall be given in the following manner.

5.9.1 Microbial limit test report: MLT/0001/00

5.9.2 Antibiotic Assay: ABA/0001/00

5.9.3 Plate Exposure report tablets: PET/0001/00

5.9.4 Finger dab test report: FDR/0001/00

e.g. For Microbial test limit

MLT	/	0001	-	00

MLT Microbial lest limit samples

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

			/					-		

_____ _____ _____

MLT Code No. Revision

5.10 All analytical Data sheet for reagent sample analysis report shall have been ten characters

e.g. Reagent Sample

RS	/	0001	-	00

RS Reagent samples

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

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_____ _____ _____

RS Code No. Revision no.

5.11 All analytical Data sheet for R&D or regulatory analysis report shall have been nine characters.

e.g.

M	/	0001	-	00

M Market Sample.

/ Slash

0001 Code No of the Materials / Products

- Dash

00 Last two digit are revision , represented as:

M	/					-		

___ _____ _____

M Code No. Revision no.

6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP – Standard Operating Procedure

7.0 REFERENCE(S):

NA

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8.0 ANNEXURE(S):

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9.0 REVISION CARD:

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