

STANDARD OPERATING PROCED	URE
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
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RM Raw Materials

/ Slash



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Supers	edes: Nil	Review Date:		
Issue D	Date:	Page No.:		
	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	l 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:



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5.4.2	AR Number	for Inprocess	sample report	will consist	of 10 char	acters.
	e.g. For Inpro	ocess Sample				
	IP /	0001	- 00			
	IP Inpro	cess Sample				
	/ Slash					
	0001 Code 1	No of the Ma	terials / Produc	ets		
	- Dash					
	00 Last ty	wo digit are re	evision , repres	ented as:		
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	IP	Code	e No.	Re	vision	
5.5	For Validati	on Samples:				
5.5.1	All analytical	Data sheets	for validation s	samples sha	l have 11	characters.
	e.g. For Valio	dation sample				
	VAL /	0001	- 00			
	VAL Valid	ation sample				
	/ Slash					

0001 Code No of the Materials / Products



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		IC W	/	00			00								
		RW	Raw w	ater s	sample										
		/	Slash												
		0001	Code N	lo of	the Mat	terials	/ Proc	lucts							
		-	Dash												
		00	Last two	o digi	it are re	visior	n, repr	esente	d as	:					
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		RW			Co	de No).			Re	vision				
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		PW	Purified	d wat	er samp	ole									



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5.7		re ship											
5.7.1	All an	nalytical	Data	Sheet	for pre s	shipmer	t or free	samp	ole shal	l have 1	0 charact	ers.	
	e.g.												

PS / 0001 - 00



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sue Date:		Page No.:
	PS Preshipment or free samples	
	/ Slash	
	0001 Code No of the Materials / Products	
	- Dash	
	00 Last two digit are revision, represented	d as:
		-
	PS Code No.	Revision
5.8	For Trial Batches:	
5.8.1	All analytical Data Sheet for trial batches sha	Ill 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	
		-
	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.



PHARMA DEVILS

		QUALITY CONTROL DEPARTME	ENT	
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Supersedes: Nil			Review Date:	
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5.9.1	Microbial limit test re	port: MLT/0001/00		
5.9.2	Antibiotic Assay: AB	A/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 tes	st limit		
	MLT / 0001	- 00		
	MLT Microbial les	st limit samples		
	/ Slash	st mint sumples		
		ne Materials / Products		
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		re revision, represented as:		
		re revision, represented as.		
	MLT	Code No.	Revision	
5.10	All analytical Data sh characters e.g. Reagent Sample	eet for reagent sample analysi	s report shall have been ten	
	RS / 0001	- 00		
	RS Reagent sam	ples		
	/ Slash			
	0001 Code No of th	ne Materials / Products		
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	QUALITY CONTROL DEPARTMENT	
	STANDARD OPERATING PROCED	URE
Department: Qu	ality Control	SOP No.:
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Supersedes: Nil		Review Date:
Issue Date:		Page No.:
	RS Code No. Revisio	
		лі но.
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	DEFEDENCE(S).	
/.U	REFERENCE(S): NA	



STANDARD OPERATING PROCEDURE

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8.0 ANNEXURE(S):

-----Nil-----

9.0 **REVISION CARD:**

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