



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Data Sheet Management	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for the Preparation, Numbering, Approval, Authorization, Control, and Revision of Data Sheet to be used in the Quality Control laboratory.

2.0 SCOPE:

This SOP is applicable for all Data sheet of Finished Product, in process, Raw material, Packaging material and Micro testing.

3.0 RESPONSIBILITY - Execution - Executive QC.

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1. After the receipt of control copy of the Specification and Standard Test Procedure from CQA/QA department, QC department shall prepare respective Data sheets.

5.2 The front page, subsequent pages, and Certificate of Analysis of Data sheets shall be prepared on the approved format on A-4 size paper. (Refer: Annexure-I for Raw Material, Annexure-II for Packing Material,

Annexure-III for Finish Product, Annexure-VII for micro GTP, Annexure -VIII for Water testing, & XI for In process / Miscellaneous And Validation samples.

5.3 Each Data sheet shall have a unique number. Once number is allocated to any Data sheet the same number shall not be repeated to other Data sheets. All types of data sheets shall be numbered as D/ Specification No./ YY

Where

D = Data sheet

/ = Separator

Specification No = unique for every material / product

YY = Revision No.

5.4 Data sheets of GTP shall be numbered as D/ GTP No./ YY

Where

D = Data sheet

/ = Separator

YY = Revision No.

5.5 After initiation, approval, and authorization of Data sheet, the Master copy shall be submitted to QA documentation cell.

5.6 QA department shall issue a photocopy by stamping on the back side of each page as a "OPERATIONAL COPY FOR PHOTOCOPYING"

5.7 Take a photocopy of operational copy for use by authorized person (Section In-charge).

5.8 Maintain issuance record with respective details as per Annexure-IV, V,VI for RM, FP, PM Annexure - IX & X for GTP (Micro) & water testing respectively, XII for In process /Miscellaneous And Validation samples.



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5.9 All the data sheets shall be reviewed whenever any change in specification or itesting procedure amended by the pharmacopoeia or relevant source.

5.10 Any change in data sheet shall be done through Change Control Procedure

5.11 After revision, Master copy of data sheet shall be submitted to QA documentation cell for control and issuance.

6.0 SAFETY & PRECAUTIONS:

Not applicable

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

No. : Number

A.R. No. : Analytical Report Number

STP : Standard Test Procedure

GTP : General Test Procedure

PM : Packaging Material

RM : Raw Material

FP : Finish Products

ANNEXURES:



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Annexure-I: Data Sheet for Raw Material

Annexure-II: Data Sheet for Packing Material

Annexure-III: Data Sheet for Finish Products

Annexure-IV: Data Sheet Issuance Record for Raw Material

Annexure-V: Data Sheet Issuance Record for Finish Product

Annexure-VI: Data Sheet Issuance Record for Packing Material

Annexure-VII: Data Sheet for GTP (Micro)

Annexure-VIII: Data Sheet for Water Testing

Annexure-IX: Data Sheet Issuance Record for GTP (Micro)

Annexure-X: Data Sheet Issuance Record for Water Testing

Annexure-XI: Data Sheet for In process / Miscellaneous And Validation sample

**Annexure-XII: Data Sheet Issuance Record for In process / Miscellaneous And
Validation sample**



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ANNEXURE-I DATA SHEET FORMAT FOR RAW MATERIAL

NAME OF RAW MATERIAL:	
SPECIFICATION DETAILS	STANDARD TEST PROCEDURE DETAILS
Specification No. :	STP No. :
Effective Date :	Effective Date :
MATERIAL DETAILS	
Batch No. :	
A.R No. :	

DATA SHEET DETAILS

Data Sheet No. :	Issued by :
Effective Date :	Issued Date :

	PREPARED BY	CHECKED BY	APPROVED BY	
Signature				
Designation				
Department	QUALITY CONTROL	QUALITY CONTROL	QUALITY CONTROL	QUALITY ASSURANCE
Date				

AR No. _____

Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by & date _____

(2) Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply



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Analysed by : **Checked by** : **Approved by** :

Date : **Date** : **Date** :



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CERTIFICATE OF ANALYSIS

Name of Material :	Reference :	IP/ BP/ USP/ IH		
Material Code :	Specification No. :			
Batch No. :	Challan No. & Date :			
AR. No. :	Received Quantity :			
Supplied By :	Sampled Quantity :			
Mfg. Date :	Date of Receipt :			
Exp. Date :	Date of Report :			
Sr. No.	Tests	Release Limits	Results	Methods

Remarks: Complies / Does not comply as per IP/ BP/ USP/ IH specification.

Analysed by : **Checked by :** **Approved by :**

Date : **Date :** **Date :**



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ANNEXURE-II DATA SHEET FORMAT FOR PACKING MATERIAL

NAME OF PACKING MATERIAL:	
SPECIFICATION DETAILS	STANDARD TEST PROCEDURE DETAILS

Specification No. :	STP No. :
Effective Date :	Effective Date :
MATERIAL DETAILS	
Batch No. :	A.R No. :

DATA SHEET DETAILS

Data Sheet No. :	Issued by :
Effective Date :	Issued Date :

	PREPARED BY	CHECKED BY	APPROVED BY	
Signature				
Designation				
Department	QUALITY CONTROL	QUALITY CONTROL	QUALITY CONTROL	QUALITY ASSURANCE
Date				

AR No. _____

Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by & date _____



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(2) **Test Name:** _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by : _____ **Checked by :** _____ **Approved by :** _____

Date : _____ **Date :** _____ **Date :** _____



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CERTIFICATE OF ANALYSIS

Name of Material :	Reference :	IP/ BP/ USP/ IH		
Material Code :	Specification No. :			
Batch No. :	Challan No. & Date :			
AR. No. :	Received Quantity :			
Supplied By :	Sampled Quantity :			
Mfg. Date :	Date of Receipt :			
Exp. Date :	Date of Report :			
Sr. No.	Tests	Release Limits	Results	Methods

Remarks: Complies / Does not comply as per IP/ BP/ USP/ IH specification.

Analysed by : **Checked by :** **Approved by :**

Date : **Date :** **Date :**



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ANNEXURE-III DATA SHEET FORMAT FOR FINISHED PRODUCT

PRODUCT NAME	
GENERIC NAME	
LABEL CLAIM	
SHELF LIFE	

SPECIFICATION DETAILS	STANDARD TEST PROCEDURE DETAILS
-----------------------	---------------------------------

Specification No. :	STP No. :
Effective Date :	Effective Date :
	MATERIAL DETAILS
	Batch No :
	A.R No :

DATA SHEET DETAILS

Data Sheet No. :	Issued by :
Effective Date :	Issued Date :

	PREPARED BY	CHECKED BY	APPROVED BY	
Signature				
Designation				
Department	QUALITY CONTROL	QUALITY CONTROL	QUALITY CONTROL	QUALITY ASSURANCE
Date				

AR No. _____

(1) Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply



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Analysed by & date _____

(2) Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by : Checked by : Approved by :
Date : Date : Date :



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CERTIFICATE OF ANALYSIS

Name of Product :	Batch No	
Generic Name :	Mfg. Date	
Label Claim :	Exp. Date	
	Report No.	
	Approval Date	
	Advice slip No.	
	Receipt Date	
Batch size: Sample size :	Specification No./	
Analysis as per:		

S.No.	Tests	Limits	Results

Remarks: Complies/ Does not comply as per IP/ BP / USP/ IH specification.

Analysed by : **Checked by** : **Approved by** :
Date : **Date** : **Date** :



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ANNEXURE-VII DATA SHEET FOR GTP (MICRO)

NAME OF PRODUCT/MATERIAL :	
GTP DETAILS	DATA SHEET DETAILS
GTP No. : Effective Date :	Data Sheet No. : Effective Date :
TESTING DETAILS	ISSUANCE DETAILS
Date of Testing : _____ Date of Release : _____ Released by. : _____	A.R. No : _____ Issued By : _____ Issued Date : _____

DATA SHEET

	Prepared By	Checked By	Approved By	
Signature				
Name				
Department	Quality Control	Quality Control	Quality Control	Quality Assurance
Date				

NAME OF PRODUCT/MATERIAL :

Step by Step details of raw data:

Analysed by & date _____

Checked by & date _____



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ANNEXURE-VIII

DATA SHEET FOR WATER TESTING

TYPE OF WATER:	
SPECIFICATION DETAILS	METHOD OF ANALYSIS DETAILS
Specification No.: Effective Date :	STP No. : Effective Date :
DATA SHEET DETAILS	SAMPLING DETAILS
Data sheet No. : Effective Date :	Sampling Date : _____ Sampling Point under test I. D. No.: _____
ISSUANCE DETAILS	
A.R. No : _____ Issued By : _____ Issued Date: _____	
TESTING DETAILS	
Date of Testing : _____ Date of Release : _____ Released by : _____	

	PREPARED BY	CHECKED BY	APPROVED BY	
Signature				
Designation				
Department	QUALITY CONTROL	QUALITY CONTROL	QUALITY CONTROL	QUALITY ASSURANCE
Date				



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ANNEXURE-XI

DATA SHEET FORMAT FOR IN PROCESS / MISCELLANEOUS AND VALIDATION SAMPLE

SAMPLE NAME	
TYPE OF SAMPLE	
LABEL CLAIM / QUANTITY	

SPECIFICATION DETAILS	STANDARD TEST PROCEDURE DETAILS
-----------------------	---------------------------------

Specification No. :	STP No. :
Effective Date :	Effective Date :
	MATERIAL DETAILS
	Batch No. :
	A.R No. :

DATA SHEET DETAILS

Data Sheet No. :	Issued by :
Effective Date :	Issued Date :

	PREPARED BY	CHECKED BY	APPROVED BY	
Signature				
Designation				
Department	QUALITY CONTROL	QUALITY CONTROL	QUALITY CONTROL	QUALITY ASSURANCE
Date				

AR No. _____

(1)Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by & date _____



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(2) Test Name: _____

Instrument ID. No. : _____

Complies/Does not comply

Analysed by : Checked by : Approved by : :

Date : Date : Date : :

