

STANDARD OPERATING PROCE	EDURE
Department: Quality Control	SOP No.:
Title: Data Sheet Management	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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

 \overline{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:

Сору			Issuance Record			lrawal ord		uction cord
No.	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	Ву	Sign/ Date	Ву	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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Date : Date : Date :



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Label Clain	n :			Exp. Date		
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ANNEXURE-IV DATA SHEET ISSUANCE RECORD FOR RAW MATERIAL

MATERIAL NAME:

A. R. No.	Issued By/Date	Received By/Date	Remarks
	A. R. No.	A. R. No. Issued By/Date	A. R. No. Issued By/Date Received By/Date



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ANNEXURE-V DATA SHEET ISSUANCE RECORD FOR FINISH PRODUCT

PRODUCT NAME:	

S.No.	Batch No.	Issued By/ Date	Received By /Date	Remarks



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ANNEXURE-VI DATA SHEET ISSUANCE RECORD FOR PACKING MATERIAL

MATERIAL NAME:

S.No.	A.R. No.	Issued By/Date	Received By/Date	Remarks



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Signature	Prepared By	DATA :		Appr	oved By	
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Name Department	Prepared By Quality Control	T	d By	Appr Quality Control	oved By Quality Assurance	
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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 :
	SAMPLING DETAILS
DATA SHEET DETAILS	Sampling Date :
Data sheet No. : Effective 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	
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ANNEXURE-IX DATA SHEET FOR GTP (MICRO)

I RODUCT NAME	PRODUCT NAME:	
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S. No.	Product Name	Batch No.	Issued By/ Date	Received By /Date	Remarks



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ANNEXURE-X DATA SHEET ISSUANCE RECORD FOR WATER

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ANNEXURE-XII DATA SHEET ISSUANCE RECORD FOR IN PROCESS / MISCELLANEOUS AND VALIDATION SAMPLE

S.No.	Product Name	AR. No.	Issued by/Date	Received by / Date	Remarks
			•		

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