PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation of Specifications	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for the Preparation, Approval, Authorization, Control, and Revision of Specification for Raw Materials (RM) ,Finish Products (FP) , In process (IP) and Packaging material (PM).

2.0 SCOPE:

This SOP shall be applicable to all Pharmacopoeial and Non Pharmacopoeial RM, FP, IP and PM Specifications to be prepared.

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

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 The specifications for the Water shall be prepared as per respective Pharmacopoeias on Annexure – I

5.2 The specifications for the Raw Materials shall be prepared as per respective Pharmacopoeias on Annexure II or prepare as per In house requirements.

5.3 The Specification for In process Materials shall be prepared as per Annexure - III

5.4 For Finished Products (FP) And Packaging material (PM):

5.4.1 After receipt of controlled copy of the specification from QA /CQA/ PRC, QC Department shall prepare the Specification as on approved format (refer Annexure – IV for FP & Annexure – V for PM)

5.5 The specifications shall be prepared on A-4 size paper

5.6 The Tests and their Limits shall be clearly specify in the specifications.

5.7 Each Specification shall have a unique number. Once a number is allocated to any Specification the same number shall not be repeated to any other Specification.

5.8 The numbering system of the Specifications shall be 5 digit alphanumeric & are as follow

Type	First & Second Character	Third, Forth & Fifth Character
Water	WA	XXX

Raw Materials	RM	XXX
Packaging material	PM	XXX
Finish Products	FP	XXX
In process	IP	XXX

Where :

WA = Water

RM = Raw Materials

PM = Packaging material

FP = Finish Products

IP = In process

XXX = Serial No. starting from 001

For example , The first Specification No. of water shall be written as WA001

5.9 After initiation, approval, and authorization of Specification, the Master copy shall be submitted to QA for control and issuance .

5.10 All the specifications shall be reviewed after two years from the effective date and whenever there is any change in pharmacopoeia or relevant source.

5.11 Any change in Specifications shall be done through change control procedure

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

STANDARD OPERATING PROCEDURE	
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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:

Documentation Control, SOP

Change Control Procedure, SOP

10.0 ABBREVIATIONS & ANNEXURES:

QC : Quality Control

No. : Number

STP : Standard Test Procedure

RM : Raw Material

FP : Finished Product

IP : In process

PM : Packing Material

QA : Quality Assurance

CQA : Corporate Quality Assurance

PRC : Promed Research Centre

ANNEXURES :

Annexure I : Format for Specification of Water

Annexure II : Format for Specification of Raw Materials

Annexure III : Format for Specification of In process

Annexure IV : Format for Specification of Finished Products

Annexure-V : Format for Specification of Packaging materials

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ANNEXURE-I

FORMAT FOR SPECIFICATION OF WATER

Name of Water			
Item Code		Page No.	1 of Y
Reference		Effective Date	
Specification No.		Review Date	

APPROVAL DETAILS:

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

Revision History

Revision No.	Reason for Revision	Supersedes No.

WATER SPECIFICATION

Name of Water			
Item Code			
Reference		Page No.	2 of Y
Specification No.		Effective Date	
STP No.		Review Date	

SPECIFICATIONS

Sr. No.	Test Parameter	Specification
1.		
2.		
3.		
4.		

5.		
6.		
7.		
8.		

WATER SPECIFICATION

Name of Water			
Item Code			
Reference		Page No.	Y of Y
Specification No.		Effective Date	
STP No.		Review Date	

Sampling Procedures:

Sample quantity:

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ANNEXURE-II

SPECIFICATION OF RAW MATERIAL

Name of Raw Material			
Item Code			
Reference		Page No.	1 of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

APPROVAL DETAILS:

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

Revision History

Revision No.	Reason for Revision	Supersedes No.

RAW MATERIAL SPECIFICATION

Name of Raw Material			
Item Code			
Reference		Page No.	2of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

SPECIFICATIONS

S.No.	Test Parameter	Specification
1.		
2.		
3.		

4.		
5.		
6.		
7.		
8.		

RAW MATERIAL SPECIFICATION

Name of Raw Material			
Item Code			
Reference		Page No.	Y of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

Acceptable container:

Sampling Procedure :

Sample Quantity :

Approved vendor :

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ANNEXURE-III

FORMAT FOR SPECIFICATION OF IN PROCESS

IN PROCESS SPECIFICATION

Name of In Process Material			
Item Code		Page No.	1 of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

APPROVAL DETAILS:

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

Revision History

Revision No.	Reason for Revision	Supersedes No.

IN PROCESS SPECIFICATION

Name of In Process Material			
Item Code		Page No.	2 of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

SPECIFICATIONS

Sr. No.	Test Parameter	Specification
1.		
2.		
3.		
4.		

STANDARD OPERATING PROCEDURE	
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5.		
6.		
7.		
8.		

IN PROCESS SPECIFICATION

Name of In Process Material			
Item Code		Page No.	Y of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

Sampling Procedures:

Sampling Quantity :

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ANNEXURE-IV

SPECIFICATION OF FINISHED PRODUCTS

Name of Product			
Item Code		Page No.	1 of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

APPROVAL DETAILS :

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

Revision History

Revision No.	Reason for Revision	Supersedes No.

Packing:

FINISHED PRODUCTS SPECIFICATION

Name of Product			
Item Code		Page No.	2 of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

SPECIFICATIONS :

Sr. No.	Test Parameter	Specification
1.		
2.		
3.		

4.		
5.		
6.		
7.		
8.		

FINISHED PRODUCTS SPECIFICATION

Name of Product			
Item Code		Page No.	Y of Y
Generic Name		Specification No.	
Label Claim		Effective Date	
Reference		Review Date	
Supersede		Shelf Life	

Storage Conditions:

Sampling Procedures:

Sample Quantity:

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ANNEXURE-V

FORMAT FOR SPECIFICATION OF PACKING MATERIAL

PACKING MATERIAL SPECIFICATION

Name of Packing Material			
Item Code			
Reference		Page No.	1 of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

APPROVAL DETAILS :

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

Revision History

Revision No.	Reason for Revision	Supersedes No.

PACKING MATERIAL SPECIFICATION

Name of Packing Material			
Item Code			
Reference		Page No.	2 of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

SPECIFICATIONS :

Sr. No.	Test Parameter	Specification
1.		
2.		
3.		

4.		
5.		
6.		
7.		
8.		

PACKING MATERIAL SPECIFICATION

Name of Packing Material			
Item Code			
Reference		Page No.	Y of Y
Specification No.		Effective Date	
Supersede		Review Date	
Storage Condition		Shelf Life	

Acceptable container :

Sampling Procedure :

Sample Quantity :

Approved vendor :