

OUALITY CONTROL DEPARTMENT

STANDARD OPERATING PRO	CEDURE
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

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



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.:

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



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.:

8.0 DISTRIBUTION:

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



		STANDARD OP	ERATING PROCE	EDURE	
Department	: Quality Control			SOP No.:	
Title: Prepar	ation of Specificatio	ens		Effective	Date:
Supersedes:				Review D	ate:
Issue Date:				Page No.:	
		ANN	EXURE-I		
	F	ORMAT FOR SPEC	CIFICATION OF WA	TER	
Name of Water	r				
Item Code			Page No.		1 of Y
Reference			Effective		
Specification N	No.		Review I	Date	
APPROVAL	DETAILS:				
		Name	Signature	Da	te
Prepared By	Quality Control		-		
Checked By	Quality Control				
Checked By	Quality Assurance				
Approved By	Quality Control				
	Quality Assurance				
Revision Historican No.	ory	Reason for Re	vision	Su	persedes No.
		WATER SI	PECIFICATION		
Name of Water	r				
Item Code			1 50 000		0 637
Reference			Page No.		2 of Y
Specification N	No.		Effective		
STP No.			Review I	Date	
SPECIFICAT	TIONS				
Sr. No.	Test Parame	eter	Sp	ecification	
1.					
2.					
3.					
4.					



	STANDARD (OPERATING PI	ROCEDURE	
Department: Quality Contro	1		SOP N	[o.:
Title: Preparation of Specifica	ations		Effecti	ve Date:
Supersedes: Nil			Reviev	v Date:
Issue Date:			Page N	lo.:
5.				
6.				
7.				
8.				
Name of Water	WAIER	SPECIFICATION		
Item Code				
Reference			ige No.	Y of Y
Specification No. STP No.			fective Date eview Date	
			THE WEST	
Sampling Procedures:				
Sample quantity:				



031499			VIA DEVII NTROL DEPARTN	. –		
		STANDARD OP	ERATING PROCE	EDURE		
Department:	Quality Control			SOP No.:		
Title: Prepara	ation of Specification	ns		Effective	Date:	
Supersedes:	Nil			Review D	ate:	
Issue Date:				Page No.:		
			EXURE-II OF RAW MATERIA	AL		
Name of Raw I	Material					
Item Code						
Reference			Page No		1 of Y	
Specification N	lo.		Effective			
Supersede			Review 1			
Storage Condit	ion		Shelf Lif	fe		
APPROVAL I	DETAILS:					
		Name	Signature	Da	ite	
Prepared By	Quality Control					
Checked By	Quality Control					
спескей Ву	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.		



	STANDARD OP	ERATING PROCE	DURE	
Department: Quality Control			SOP No.:	
Title: Preparation of Specificat	tions		Effective Date:	
Supersedes: Nil				
Issue Date:			Page No.:	
4.				
5.				
6.				
7.				
8.				
Name of Raw Material Item Code			1	
Reference		Page No.	Y of	Y
Specification No.		Effective Review D		
Supersede Storage Condition		Shelf Life		
Storage Condition		Shen End		
Acceptable container:				
Sampling Procedure:				
Sample Quantity:				
Approved vendor:				



3.

PHARMA DEVILS

			QUALITYCO	NIKOL D	EPAKINI	ENI		
			STANDARD OI	PERATIN(G PROCE	DURE		
Departmen	nt: Quality Contro	ol				SOP N	o.:	
	aration of Specific		ıs			Effecti	ve I	Date:
Supersedes						Reviev	v Da	nte:
Issue Date:						Page N	lo.:	
			ANN	EXURE-III				
		FOR	MAT FOR SPECI			OCESS		
			IN PROCESS	S SPECIFICA	ATION			
	Process Material							
Item Code			Page No.				1 of Y	
Generic Nam	ne				Specificat			
Label Claim					Effective			
Reference					Review D			
Supersede					Shelf Life	2		
APPROVAL	L DETAILS:							
			Name	S	Signature		Dat	e
Prepared By	Quality Contro							
Checked By	Quality Contro							
Checked by	Quality Assura	nce						
Approved By	Quality Control							
- Inpproved Dy	Quality Assura	nce						
Revision Hi	story							
Revision No.			Reason for R	evision			Sup	ersedes No.
Nama of In I	Process Material		IN PROCESS	S SPECIFICA	ATION			
Item Code	10008 Material	+			Page No.			2 of Y
Generic Nam	10	+			Specificat	tion No	l	2 UI I
Label Claim	10	+			Effective			
Reference			Review I					
Supersede		+	Shelf Life					
SPECIFICA	TIONS				1 Shell Life			
Sr.	Test Pa	ameter	<u>, </u>		Sne	ecification		
No.	10511 a	amete	•					
1.								
2.								



Fitle: Preparation of Specifications Supersedes: Nil Review Date: Page No.: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Seneric Name Selection No. Subsel Claim Selection	Title: Preparation of Specifications Supersedes: Nil Review Date: Page No.: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Seneric Name -abel Claim Reference Supersede Sampling Procedures: Sampling Procedures:	Title: Preparation of Specifications Supersedes: Nil Review Date: Page No.: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Seneric Name -abel Claim Reference Supersede Sampling Procedures: Sampling Procedures:	Effective Date: Supersedes: Nil	Fitle: Preparation of Specifications Supersedes: Nil Sesue Date: 5. 6. 7. 8. IN PROCESS SPECIFICATION Same of In Process Material tem Code tem Code Scherric Name Jabel Claim Scherric Name Sc	Title: Preparation of Specifications Supersedes: Nil Review Date: Page No.: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Seneric Name abel Claim Seneric Name Abel Claim Reference Review Date Supersede Sampling Procedures:		TANDARD OPERATING P	KUCEDURE
Review Date:	Supersedes: Nil Review Date:	Review Date: Same Date: Page No.:	Review Date: Page No.:	Supersedes: Nil Same Date: 5. 6. 7. 8. IN PROCESS SPECIFICATION Same of In Process Material Sem Code Seneric Name Jabel Claim Selective Date Selective Date Supersede Shelf Life Sampling Procedures:	Review Date:	Department: Quality Control		SOP No.:
S. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seperic Name Jeffective Date Reference Review Date Supersede Sampling Procedures:	Ssue Date: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seperic Name Jeffective Date Reference Supersede Sampling Procedures:	S. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seperic Name Jeffective Date Reference Supersede Sampling Procedures:	Issue Date: 5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material frem Code Seperic Name Label Claim Reference Review Date Supersede Sampling Procedures:	S. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code tem Code Seneric Name Specification No. Sabel Claim Sefference Seference Supersede Sampling Procedures:	Sampling Procedures: Page No.:	Title: Preparation of Specifications		Effective Date
5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seperic Name Specification No. Sabel Claim Effective Date Seference Review Date Supersede Shelf Life Sampling Procedures:	5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Specification No. Label Claim Reference Review Date Supersede Sampling Procedures:	5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seperic Name Label Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Specification No. Label Claim Effective Date Reference Review Date Supersede Supersede Shelf Life Sampling Procedures:	5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code tem Code Seneric Name Specification No. Sabel Claim Effective Date Seference Review Date Supersede Shelf Life Sampling Procedures:	5. 6. 7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code tem Code Seperic Name Label Claim Seference Supersede Supersede Sampling Procedures:	Supersedes: Nil		Review Date:
IN PROCESS SPECIFICATION Same of In Process Material tem Code Tem	IN PROCESS SPECIFICATION Same of In Process Material tem Code Tem	IN PROCESS SPECIFICATION Same of In Process Material tem Code tem Code Seneric Name Specification No.	IN PROCESS SPECIFICATION Same of In Process Material tem Code tem Code Seneric Name Specification No. Sabel Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Same of In Process Material tem Code tem Code Seneric Name Specification No. Sabel Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Same of In Process Material tem Code tem Code Specification No. Label Claim Reference Review Date Represede Shelf Life Sampling Procedures:	Issue Date:		Page No.:
TIN PROCESS SPECIFICATION Same of In Process Material tem Code Generic Name Jabel Claim Seffective Date Review Date Supersede Sampling Procedures:	TIN PROCESS SPECIFICATION Same of In Process Material Tem Code T	TIN PROCESS SPECIFICATION Same of In Process Material Tem Code T	7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seneric Name Specification No. Label Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Specification No. Label Claim Reference Review Date Supersede Sampling Procedures:	7. 8. IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seneric Name Specification No. Label Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	5.		
IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Specification No. Label Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material Item Code Seneric Name Label Claim Reference Review Date Supersede Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Jabel Claim Reference Review Date Supersede Sampling Procedures:	6.		
IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Specification No. Label Claim Seference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Tem	IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Teneric Name Jabel Claim Reference Review Date Supersede Sampling Procedures:			
IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material Item Code Page No. Specification No. Label Claim Reference Review Date Supersede Supersede Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	7.		
IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Generic Name Specification No. Label Claim Reference Review Date Supersede Supersede Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	IN PROCESS SPECIFICATION Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	0		
Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Effective Date Reference Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Seneric Name Specification No. Label Claim Seference Supersede Supersede Sampling Procedures:	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Te	Name of In Process Material tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Supersede Shelf Life Sampling Procedures:	8.		
Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Te	Name of In Process Material tem Code Te	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:			
Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Page No. Y of Y Generic Name Specification No. Label Claim Effective Date Review Date Supersede Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Seneric Name Specification No. Label Claim Seference Supersede Supersede Sampling Procedures:	Name of In Process Material tem Code Tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material tem Code Te	Name of In Process Material tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Supersede Shelf Life Sampling Procedures:			
tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	tem Code Generic Name Specification No. Label Claim Reference Review Date Supersede Supersede Sampling Procedures:	tem Code Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	tem Code Generic Name Specification No. Label Claim Reference Review Date Supersede Supersede Sampling Procedures:	tem Code Seneric Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	tem Code Generic Name Specification No. Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Name of In Process Material	IN PROCESS SPECIFICATI	ON
Generic Name Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Generic Name Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Generic Name Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Generic Name Label Claim Effective Date Reference Review Date Supersede Shelf Life Sampling Procedures:	Generic Name Label Claim Effective Date Reference Review Date Shelf Life Sampling Procedures:	Generic Name Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:		Pa	age No. Yo
Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:	Label Claim Reference Review Date Supersede Shelf Life Sampling Procedures:		Sı	pecification No.
Review Date upersede Shelf Life Sampling Procedures:	Review Date upersede Shelf Life Sampling Procedures:	Review Date upersede Shelf Life Sampling Procedures:	Review Date upersede Shelf Life Sampling Procedures:	Review Date upersede Shelf Life Sampling Procedures:	Review Date upersede Shelf Life Sampling Procedures:		E	ffective Date
Sampling Procedures: Shelf Life	Sampling Procedures: Shelf Life	Sampling Procedures: Shelf Life	Sampling Procedures:	Sampling Procedures:	Sampling Procedures:			
Sampling Procedures:	Sampling Procedures:							



3.

PHARMA DEVILS

Department	: Quality Control		ERATING PROCED	OP No.:	<u> </u>
	ation of Specification	 ns		Effective	
Supersedes:		113		Review D	
	1111				
Issue Date:				age No.:	•
	S		XURE-IV FINISHED PRODUCT	ΓS	
Name of Produ	ıct				
Item Code			Page No.		1 of Y
Generic Name			Specificatio		
Label Claim		_	Effective D		
Reference Supercode			Review Dat Shelf Life	i.e	1
Supersede			Shell Life		
APPROVAL	DETAILS :				
		Name	Signature	Da	ate
Prepared By	Quality Control				
Checked By	Quality Control Quality Assurance				
	Quality Assurance Quality Control				
Approved By	Quality Assurance				
Revision Hist Revision No.	ory	Reason for Rev	/ision	Su	ipersedes No.
Packing:	-				
		FINISHED PRODU	CTS SPECIFICATION		
Name of Produ	ıct	FINISHED PRODU			
Item Code		FINISHED PRODU	Page No.		2 of Y
Item Code Generic Name		FINISHED PRODU	Page No. Specificatio		2 of Y
Item Code Generic Name Label Claim		FINISHED PRODU	Page No. Specificatio Effective D	ate	2 of Y
Item Code Generic Name Label Claim Reference		FINISHED PRODU	Page No. Specificatio Effective Defective Defe	ate	2 of Y
Item Code Generic Name Label Claim Reference		FINISHED PRODU	Page No. Specificatio Effective D	ate	2 of Y
Item Code Generic Name Label Claim Reference Supersede		FINISHED PRODU	Page No. Specificatio Effective Defective Defe	ate	2 of Y
Item Code Generic Name Label Claim Reference			Page No. Specificatio Effective Dat Review Dat Shelf Life	ate	2 of Y
Item Code Generic Name Label Claim Reference Supersede SPECIFICAT	TIONS :		Page No. Specificatio Effective Dat Review Dat Shelf Life	ate e	2 of Y
Item Code Generic Name Label Claim Reference Supersede SPECIFICAT Sr. No.	TIONS :		Page No. Specificatio Effective Dat Review Dat Shelf Life	ate e	2 of Y
Item Code Generic Name Label Claim Reference Supersede SPECIFICAT Sr.	TIONS :		Page No. Specificatio Effective Dat Review Dat Shelf Life	ate e	2 of Y



	STANDARD	OPERATING PROC	CEDURE		
Department: Quality Contr	ol		SOP No.	•	
Title: Preparation of Specific	cations		Effective	Date:	
Supersedes: Nil			Review I	Date:	
Issue Date:			Page No.	:	
			<u> </u>		
4.					
5.					
J					
6.					
-					
7.					
8.					
0.					
	FINISHED PRO	DDUCTS SPECIFICAT	ION		
Name of Product					
Item Code		Page N	No.	Y of Y	
Generic Name		Specif	ication No.		
Label Claim			ive Date		
Reference Supersede		Review Shelf I			
Supersede		Shen i			
Storage Conditions:					
Sampling Procedures:					
Sample Quantity:					



		STANDARD OP	ERATING	PROCEDUR	E	
Department	: Quality Control			SOP	No.:	
Title: Prepara	ation of Specification	ns		Effe	ctive	Date:
Supersedes:	-				iew D	
	1411			-		
Issue Date:				Page	e No.:	
	FORMAT	ANNI Γ FOR SPECIFICAT	EXURE-V FION OF PA	ACKING MAT	ERIA	L
		PACKING MATER	RIAL SPECI	FICATION		
Name of Packi	ng Material					
Item Code						
Reference				Page No.		1 of Y
Specification N	Vo.			Effective Date		
Supersede				Review Date		
Storage Condit	ion			Shelf Life		
APPROVAL	DETAILS :	l N				
D 1 D	O1' C1	Name	S	ignature	Da	ite
Prepared By	Quality Control					
Checked By	Quality Control					
<u> </u>	Quality Assurance Quality Control					
Approved By	Quality Assurance					
Revision Historican No.	ory	Reason for Re	evision		Su	persedes No.
Name of Packi	ng Material	PACKING MATER	RIAL SPECI	FICATION	l	
Item Code						
Reference				Page No.		2 of Y
Specification N	Vo.			Effective Date		
Supersede				Review Date		
Storage Condition				Shelf Life		
Storage Condit	.1011	_		Shell Life		
SPECIFICAT	IONS :					
Sr. No.	Test Parame	eter		Specifica	ation	
1.						
2.						
3						



		STANDARD (PERATING PR	OCEDURE		
Departm	ent: Quality Control			SOP No	·:	
Title: Pre	paration of Specificat	ions		Effective	e Date:	
Supersed	es: Nil			Review	Date:	
Issue Dat	e:			Page No).:	
				•		
4.						
5.						
6.						
7.						
8.						
		PACKING MAT	ERIAL SPECIFIC.	ATION		
	acking Material					
Item Code			D	NY	37 637	
Reference	on Mo			ge No. ective Date	Y of Y	
Specification Supersede	On NO.			view Date		1
Storage Co	ndition			elf Life		1
Acceptabl	e container :		,			_
Sampling	Procedure :					
Sample Qu	uantity:					
Approved	vendor :					