PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Conducting of Manufacturing / Packing Trials	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for conducting of manufacturing of trials to be conducted with the facility (in house) or outside.

2.0 SCOPE"

2.1 The procedure defined in the SOP is applicable only to machine or packing trials or proposed product trials. This SOP is not applicable for conducting any type of reprocessing on commercial or registration products.

3.0 RESPONSIBILITY:

3.1 Officer/ Executive: Production: Raising proposal for conducting trials and for conducting trial.

3.2 Officer/ Executive, Stores: For arranging material

3.3 IPQA - Shall ensure compliance of the SOP.

3.4 Head- Production, QA & Store - Shall ensure compliance of the SOP.

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 SOP is applicable for conducting any trial at outside and inside the facility.

5.2 It is applicable for trial of new machine, qualification, new machine change part, change part / artwork development or Product development, engineering batch or in case both raw material & packaging material is required to be used or sent to the vendor, the material may be allowed to issue as per the following procedure.

5.3 Requisition for approval of proposal shall be raised to QA. (Refer Annexure-IV) (Proposal Request for Trial Batch (Outside).

5.3.1 On issuance, the form shall be filled to provide the following information:

- Purpose of trial/ engineering batch.
- Material (raw and packing) material to be used along with quantity

5.3.2 The request shall be approved by Head, Production and forwarded to QA for review, request shall be raised by concerned department.

5.3.3 Head QA shall assess the Information for taking a decision for approval or rejection of proposal. If approved, trial shall be undertaken on completion of activities defined in the final assessment.

5.3.4 The form with other department comments shall be returned to QA for review by head, Plant and QA Head. Once approved, the material shall be sent out to the party (Reference SOP "Movement of material").

5.4 In the case in in house trial is to be conducted to reason defined in scope, the following procedure shall be followed.

5.4.1 Production department shall raise a requisition as per Annexure-III "Proposal Request For Trial Batch" to QA Head for approval. On receipt of the form, the following Information shall be filled in and approved by Head, Production.

- Proposed plan for Trial
- Equipment Usage Details (include all major equipment to be used)
- Brief description of process to be followed or provide / attach reference procedure to be followed
- Batch Size
- Material Usage details
- Obtained from R&D/ Other Site
- Proposed BOM with quantity, API details, etc.
- Sampling and testing requirement
- The filled and approve request shall be forwarded to QA for impact assessment on, at least the following:
- Impact on existing license
- Impact on Qualification of equipment/ area
- Impact of Cleaning Procedures of equipment/ area
- Impact on Cleaning Validation/ Verification

5.4.2 Following assessment, the form shall be sent to various department, identified during the review for evaluation and comments.

5.4.3 On receipt of comments from various departments, Head QA shall assess the Information for taking a decision for approval or rejection of proposal. If approved, trial shall be undertaken on completion of activities defined in the final assessment.

To conduct trial, production shall request a batch no. The assigned batch number shall be recorded on Annexure-II ""Trial Record", duly signed by QA officer, assigning the batch no.

5.4.5 The trial shall be recorded on Annexure-II "Trial Record".

The record shall be used for recording the processing of the batch including line Clearance, equipment

usage and conclusion of trial.

5.5 On conclusion of trial, the batch shall be destroyed. The destruction of the batch shall be recorded on Annexure-II.

5.6 The issuance of the raw/ packing materials shall be made by the officer / executive of user department as per Annexure-I.

5.7 The Head of department or designee shall check and sign the requisition.

5.7.1 The requisition shall be forwarded to the Head Plant and Head QA for final approval.

5.7.2 After approval, issue the material from store.

5.7.3 Printed packing material shall be defaced first then allowed to move out of factory.

5.7.4 Swab verification sample of trial batch shall not be send to Q.C. for analysis.

Note: - In case of the engineering/ trail batch, if batch size is less than one lakh tablet/capsule than trail will be conducted and reported in Annexure – II (Trial Record) and in case of batch size of trail equal to one lakh or more than one lakh, current batch record (can be of any market) shall be issued with trail batch record batch number.

6.0 ABBREVIATION(S):

6.1 QA : Quality Assurance.

6.2 SOP : Standard Operating Procedure.

6.3 P&A : Personnel and Administration.

7.0 REFERENCE(S):

7.1 SOP: Movement of Material.

7.2 SOP: Requisition, Issuance and Archival of Batch Manufacturing and Packaging Records.

8.0 ANNEXURE(S):

Annexure no.	Tittle of Annexure	Format no.	Mode of Execution
Annexure I	Requisition sheet for Raw / Packing material for performing machine trial within or outside from factory premises		Controlled format
Annexure II	Trial \ Engineering Record		Controlled format
Annexure III	Proposal Request for Trial / Engg / Pre-Exhibit Batch		Controlled format
Annexure IV	Proposal Request for Trial Batch (Outside)		Controlled format

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9.0 DISTRIBUTION:

9.1 **Master copy** **:** Quality Assurance.

9.2 **Controlled copy(s):** Production department (01), Quality Assurance (01).

9.3 **Reference copy (s):** Production department 01), Utilities (01), Store (01), P&A (01)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason(s) for revision	Details of Revision	Effective date
01	00		New SOP	NA	

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ANNEXURE I

Requisition sheet for Raw/Packing material for performing machine trial within or outside from factory premises

Reason for issuance: **Batch no.:**

S.No.	Item code	Item Name	UOM	Required Qty.	Issued Qty	A.R. Number	Issued by.	Checked by	Verified by

Prepared By Sign/Date	Checked By Sign/Date			Approved By Sign/Date	
	HOD	QA	Store	Plant Head	Head QA

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Assay Calculation: For Exact Quantity of API_____

The below calculation is to be used when standard quantity of API is to be dispensed is available from one A. R. No.

A. R. No.: _____	**Assay on anhydrous/dried basis (a1): _____%**	**Assay on as such basis (c1):** **c1 = a1 X (100 – b1) / 100 = _____%**	**Done By**	**Checked By**
	Water/LOD (b1): _____%			
Quantity of 'API' to be dispensed eq. 100% assay basis (**A1**) = Std. Qty X 100 / C1 = _____ Extra quantity of **'API'** dispensed is (**X1**) = (**A1**) – (Std. Qty.) = _____- **X1** = _____ Kg				
Excipients Name:;- _____ **Quantity of 'Excipients' to be dispensed (B1)** **B = _____ – (X1)]** **B = _____ Kg**				

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Assay Calculation: For Exact Quantity of API_____

The below calculation is to be used when standard quantity of 'API' is to be dispensed is not available from one A. R. No.

A. R. No.	Available Quantity (e1)	Assay on anhydrous/dried basis (a1) %	Water/LOD (b1) %	Assay % on as such basis (c1) = a1X(100- b1) / 100	Quantity on 100 % assay basis (d1) = (e1) X (c1) / 100	Done By	Checked By
	$e1_A$=				$d1_A$=		
	$e1_B$=				$d1_B$=		
	$e1_C$=				$d1_C$=		
Total Available Quantity (e1) **e1 = ($e1_A$+$e1_B$+$e1_C$) =**				**Total Quantity (d1)** **d1 = ($d1_A$+$d1_B$+$d1_C$) =**			
Remaining theoretical quantity of API required (f1) = Std. Qty. - (d1) (f1) = _____ - _____ = _____ Kg.							
Next A. R. No.: _____	**Assay on anhydrous / dried basis (a12): _____%** **Water / LOD (b12): _____%**			**Assay on as such basis (c12):** **c12 = a12 X (100- b12) / 100 = _____%**			

Actual Quantity of this A.R. No. to be dispensed (h1) = $\frac{(f1) \times 100}{(c12)}$ = _____ Kg Therefore total quantity of **'API'** dispensed (**A1**) = (e1) + (h1) **A1** = _____ + _____ = _____ Kg Extra quantity of **'API'** dispensed is (**X1**) = (**A1**) –_____ = _____ **X1** = _____ Kg		
Excipients Name:;- _____ **Quantity of 'Excipients' to be dispensed (B1)** **B = [_____ – (X1)]** **B = _____ Kg**		

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ANNEXURE II
Trial \ Engineering Record

Batch No. : BTZ_____

Issued By :

Line Clearance

Area Name:-

Date:-

Equipment Name	Equipment Id.	Cleaning SOP No.	Operation SOP No.

Put '√' if complies and put 'X' if does not complies in the check box.

Previous Product : _____	**Batch No.:** _____
Check the following and take line clearance from Q.A as per SOP …… Removal of previous product and batch ☐ Equipment cleanliness ☐ Area cleanliness ☐ Status Labeling ☐ Environmental condition ☐ Balance calibration record ☐ Equipment log sheets	
Rinse Report AR No. :	
Checked By (Dept.) Sign / Date	Approved By (QA) Sign / Date

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Instructions:

Follow these general precautions before starting the process.

1. Ensure that the secondary gowning of the respective area if followed.
2. Wear hand gloves, nose mask and safety goggles, and ear muffs (if required)
3. Ensure that the equipment's are cleaned and having status label.
4. Ensure the environmental conditions of the particular area. Record in the appropriate area logbook.

Process:

Equipment Usage Details:

Equipment Name/ Others	Identification No.

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Raw Material Sifting Record:-	
Vibro – Sifter ID No.: ……/…/…/_____	**Date:**
Sifting started at:	**Sifting completed at:**
Remark :-	
Checked by :-	

Raw Material Co-sifting Record	
Vibro – Sifter ID No.: …./…./…./_____	**Date:**
Sifting started at:	**Sifting completed at:**
Remark:	
Checked by:	

Granulation Parameters:-		
Dry Mixing & Granulation		
Binder addition time		
Granulation Time		
Additional Water/IPA etc. qty. used (if required)		
Additional Water/ IPA etc. qty. addition time		
Granulation time (if required)		
Total granulation time		
Agitator Amperage		

Chopper Amperage		
Extrusion and Spheronization		
Length of Extrudes (mm)		
Roller speed (RPM)		
Speed (RPM)		
Drying (FBD)		
Inlet Temperature		
Outlet Temperature		
Total Drying Time		
Drying (VTD)		
VTD chamber temperature		
Hot water inlet temperature		
Vacuum Pressure		

Process Step Description	Done By	Checked By (Sign / Date)

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LINE CLEARANCE FOR COMPRESSION AREA **Date: _____**

Equipment Name	Equipment ID No.	Cleaning SOP No.	Operation SOP No.
	…./…./…./_____	PG/___	PG/___
	…../…./…./_____	PG/___	PG/___
S. S. Container		**PG/___**	**NA**
Area			
Line Clearance Tablet Compression			
Previous Product:		Batch No.:	
Checked By (Production) (Sign & Date)		**Approved By (QA) (Sign & Date)**	

Machine Start Up & End Details							
Started At		**Done By**	**Checked By**	**Completed At**		**Done By**	**Checked By**
Date	**Time**			**Date**	**Time**		
Compress the whole batch with the above specification as given in table.							

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Before Compression Punch, Die and Cap Inspection Done By: - _____

Ist Start-up Test During Tablet Compression											**2nd start up**				
Specification			**Time:-**				**Date:-**				**Time:-**			**Date:-**	
S.No.	**Test**	**Equipment ID No.**	**Observations**								**Observations**				
1.	**Appearance:**		.												
2.	**Uniformity of Weight of____ Tablets**														
			Minimum:			**Maximum:**					**Minimum:**			**Maximum:**	
3.	**Average Weight of ___ Tablets**		**_____mg**								**_____mg**				
4.	Weight of _____ Tablets		**_____g**								**_____g**				
5.	**Thickness of _____ Tablets**														
			Minimum:			**Maximum:**					**Minimum:**			**Maximum:**	

Table No.: 3.4.1 - 1st Start-up Test During Tablet Compression (Verification of Tablet Parameters) Contd…… | **2nd start up**

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	Test	**Equipment ID No.**	**Observations**	**Observations**
	Diameter of _____ Tablets			
			Minimum: **Maximum:**	**Minimum:** **Maximum:**
	Hardness of _____ Tablets			
			Minimum: **Maximum:**	**Minimum:** **Maximum:**
	Friability NMT 1% w/w			
	Machine Speed (RPM)		**_____ RPM**	**_____ RPM**
	Hydraulic Pressure (KN)		**_____ KN**	**_____ KN**
Specification Parameters Verified By: Sign & Date			**Tablet Parameters Checked By: Sign & Date**	**Tablet Parameters Checked By: Sign & Date**

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IN-PROCESS CHECKS

Date	Time	Machine Parameter		Appearance of the Tablets (Defects)						
		Machine Speed (RPM)	Hydraulic Pressure (KN)	Capping	Chipping	Sticking	Broken Tablets	Discoloration	% Defects	Ckd By

IN-PROCESS CHECKS (Thickness, Hardness and Friability)

Date	Time	Thickness (mm) Equipment ID No.:				Hardness Equipment ID No.:		Friability NMT 1.0 % w/w Equipment ID No.	Ckd By

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IN-PROCESS CHECKS (Thickness, Hardness and Friability)									
Date	**Time**	**Thickness (mm) Equipment ID No.:**				**Hardness Equipment ID No.:**		**Friability NMT 1.0 % w/w Equipment ID No.**	**Ckd By**

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Procedure (To filled for activity which cannot be recorded in above format)

Process Step Description	Done By	Checked By (Sign / Date)

Reviewed By	Checked By	Approved By
Deptt.	Deptt.	Deptt.
Sign/Date	Sign/Date	Sign/Date

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Destruction of Batch

Date of destruction :

Mode of destruction:

Supervised by	**Approved By**	
	IPQA	**Head, Production**
Sign/Date		**Sign/Date**

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COATING **Date:**

Coating Solution Preparation Record						
Pneumatic Stirrer ID:		**Date:-**				
Step No.	**Description**	**Quantity (Kg)**	**Time**		**Done By**	**Checked By**
			From	**To**		

Coating Cycle Details					
Started At		**Completed At**		**Done By**	**Checked By (Production)**
Date	**Time**	**Date**	**Time**		

Coating Details			Date:-	
Stage	**Started At**	**Completed At**	**Done By**	**Checked By**
Loading				
Preheating				
Coating				
Drying				
Cooling				

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In-process Checking Record During Film Coating

Date	Time	Inlet Temp.	Outlet Temp.	Bed Temp.	Pan RPM (____RPM)	Peristaltic Pump RPM (____RPM)	Atomisation Pressure (____ Kg/cm^2)	Spray Rate (g/gun/min)	Supply Inlet Air Velocity (RPM)	Exhaust Air Velocity (RPM)	Wt. of 100 Tablets (g)	Done By	Ckd By

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In-process Checking Record During Film Coating

Date	Time	Inlet Temp.	Outlet Temp.	Bed Temp.	Pan RPM (____RPM)	Peristaltic Pump RPM (____RPM)	Atomisation Pressure (____ Kg/cm^2)	Spray Rate (g/gun/min)	Supply Inlet Air Velocity (RPM)	Exhaust Air Velocity (RPM)	Wt. of 100 Tablets (g)	Done By	Ckd By

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IN-PROCESS CHECKS AFTER COATING				
S.No.	**Test**	**Equipment ID No.**	**Observations 1st start up**	**Observations 2nd start up**
1.	**Appearance:**			
2.	Weight of 20 Tablets		_____ **g**	_____ **g**
3.	**Thickness of 20 Tablets**			
			Minimum: **Maximum:**	**Minimum:** **Maximum:**
4.	**Uniformity of Weight of 20 Tablets**			
			Minimum: **Maximum:**	**Minimum:** **Maximum:**
5.	Average Weight of 20 Tablets		**A1**_____ **mg**	
Tablet Parameters Checked By:-Sign & Date				**Tablet Parameters Checked By:-Sign & Date**

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Procedure (To filled for activity which cannot be recorded in above format)

Process Step Description	Done By	Checked By (Sign / Date

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Packing:

Line Clearance

Area Name:

Date:-

Equipment Name	Equipment ID	Cleaning SOP No.	Operation SOP No.

Put '√' if complies and put 'X' if does not complies in the check box.

Previous Product : _____	**Batch No.: _____**
Check the following and take line clearance from Q.A as per SOP No……. Removal of previous product and batch ☐ Equipment cleanliness ☐ Area cleanliness ☐ Status Labeling ☐ Environmental condition ☐ Balance calibration record ☐ Equipment log sheets	
Rinse Report AR No. :	
Checked By (Dept.) Sign / Date	**Approved By (QA) Sign / Date**

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Process Step Description	Done By	Checked By (Sign / Date)

Reviewed By	Checked By	Approved By
Deptt.	Deptt.	Deptt.
Sign/Date	Sign/Date	Sign/Date

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Destruction of Batch

Date of destruction :

Mode of destruction:

Supervised by	Approved By	
	IPQA	**Head, Production**
Sign/Date		**Sign/Date**

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ANNEXURE III
Proposal Request for Trial / Engg / Pre-Exhibit Batch

Document No.: _____

Section - 1 (To be filled by Production)

Initiated By:
Name: Sign. Date:

Proposed plan:- **Trial / Engg / Pre-Exhibit Batch**

1. Purpose of Plan:-
2. Equipment Usage Details (include all major equipment to be used) (use additional pages, if required and provide details are per format given below)

S.No.	Equipment Name	Equipment ID

3. Brief description of process to be followed or provide / attach reference procedure to be followed (attach additional sheets as per requirement)
4. Requirement of BMR:- Yes/No

If yes, mention BMR no.-

5. Batch Size :
6. Material Usage details

   a. Obtained from R&D/ Other Site: Yes / No. If yes, provide details. If No, move to part b.

   b. Proposed BOM with quantity, API details, etc., ((attach additional sheets as per requirement)

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S.No.	Ingredients	UOM	Quantity	Item code (If available)

Verified by	
Production (Sign/Date)	**QA (Sign/Date)**

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Section - 2 (To be filled by Quality Assurance)

Quality Assurance shall review the impact of proposed impact on the following :

1. Impact on existing license : Yes/ No
2. Impact on Qualification of equipment/ area : Yes/ No
3. Impact of Cleaning Procedures of equipment/ area : Yes/ No
4. Impact on Cleaning Validation/ Verification : Yes/ No
5. Other :
6. Sampling and testing requirements, if any:- Yes/No, If yes QA shall provide the sampling protocol approved by Head Production / Designee
7. Review required by other Dept. : Yes / No (if yes, list the department)

Approved By Head Quality assurance (Sign/Date):-

Section - 3 (Review by Other Departments)

Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :

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Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :

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Section - 4 (Disposition of Proposal)

Comments by Plant Head :

The proposal is Accepted/ Not Accepted
(Sign/ Date)

Comments by Head QA :

The proposal is Accepted/ Not Accepted
Head QA (Sign/ Date)

If approved, activities to be undertaken:

License Availability : ☐
Line Clearance Checklist : ☐
Cleaning Checklist/ Procedure : ☐
Cleaning Method Validation / Verification : ☐
Testing Method Validation / Verification : ☐
Qualification activities ☐ :
Specification : ☐
Item Code Requirement : ☐

On approval, the initiator department shall commence trial, when the above mentioned activities are completed. The issuance of material and recording of details shall be as per Annexures to the SOP No. Batch No. shall be allocated by QA.

Batch no. allotted by QA : BTZ_____

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ANNEXURE IV
Proposal Request for Trial Batch (Outside)

Document No.:_____

Section -1 (To be filled by Production)

Initiated By:

Name: Sign. Date :

Proposed plan for Trial

7. Purpose of trial :

8. Material Usage details

c. Obtained from R&D/ Other Site: Yes / No. If Yes, provide details. If No , move to part b.

d. Proposed BOM with quantity, API details, etc., ((attach additional sheets as per requirement)

S.No.	Ingredients	UOM	Quantity	Item code (If available)

Approved By (Head, Production/ designee):

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Conducting of Manufacturing / Packing Trials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Section - 2 (Reviewed by Quality Assurance)

Comments: :

Review required by other Dept. : Yes / No (if yes, list the name of department)

Reviewed By (QA) : **Approved By (Head, QA) :**

Section -3 (Review by other Departments)

Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :
Department Name :
Comments :
Sign/ Date :

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Conducting of Manufacturing / Packing Trials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Department Name :
Comments :
Sign/ Date :
Final Review Plant Head
Comments : **The proposal is Accepted/ Not Accepted** **Reviewed on Sign/ Date :**
Section - 4 (Disposition of Proposal) **Comments by Head QA :** **The proposal is Accepted/ Not Accepted** **Approved By (Head, QA) :**