ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD,SOLAN, H.P. (INDIA)
BATCH MANUFACTURING RECORD

Generic Name: Gastro-Resistant Lansoprazole Capsules BP	
BMR No.: APD/BMR/GC/GRL/021	**Revision No.:00**
BMR Supersedes No.: NIL	**Effective Date:** 26/02/2024
Batch No.:	**Batch Size:**

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Generic Name	**Gastro-Resistant Lansoprazole Capsules BP**
Label Claim	Each Hard Gelatin Capsule Contains: Lansoprazole BP 30 mg (as enteric coated pellets) Excipients: q.s. Colour: Approved Colour used in empty Capsule Shell.
Mfg. Lic. No.	S-MNB/10/93 & S-MB/10/94
MFR No.	APD/MFR/GC/GRL/021
Product Code	GRL/021
Mfg. Date	
Exp. Date	
Shelf Life	36 Months
Storage Condition	Store in a cool & dry place. Protect from direct light.
Market	
Actual Batch Size	
Issued By QA (Sign & Date)	
Issue Date	
Date of Commencement	
Date of Completion	

	Prepared By	Checked By		Approved By
Signature				
Date	26/02/2024	26/02/2024	26/02/2024	26/02/2024
Name	Guljari Lal	Manjeet Kumar	Shweta Jishtu	Pramod Katare
Designation	Asst. Manager	Manager	Sr. Executive	Manager
Department	Production	Production	Quality Assurance	Quality Assurance

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1.0 GENERAL INSTRUCTIONS:

1.1 Good manufacturing practices shall be followed during the entire process of manufacturing including sampling and dispensing.

1.2 All the containers and equipments used for manufacturing shall be properly cleaned as per the relevant SOP.

1.3 All the equipments and containers shall have proper status label as per SOP No.: APD/QAD/032.

1.4 All the equipments shall be operated as per the relevant SOP's only.

1.5 All the measuring equipments and containers shall be calibrated irrespective of the activity and use within the date of calibration as per the calibration schedule

1.6 Weights of all the materials shall be cross check by production personnel against dispensing label before taken up for manufacturing.

1.7 Overwriting in BMR and all other documents shall be strictly avoided, and if so, shall be as per APD/QAD/022.

1.8 All the operations shall be carried out in clean and orderly manner.

1.9 Any deviation in process shall be brought to knowledge of QA and prior approval of QA department shall be taken.

1.10 Critical parameters including temperature, humidity and pressure differences shall be checked and monitored APD/QAD/037 & APD/ENG/057.

1.11 In process controls shall be carried out throughout manufacturing operations as per relevant instructions defined in this BMR and relevant SOP's.

1.12 Ensure that all materials like raw materials, in process materials and finished goods shall be placed in respective areas with proper label.

1.13 Attach additional sheets wherever required

1.14 Attach system generated data recording sheets wherever applicable after proper verification.

1.15 No material shall be placed directly on the floor.

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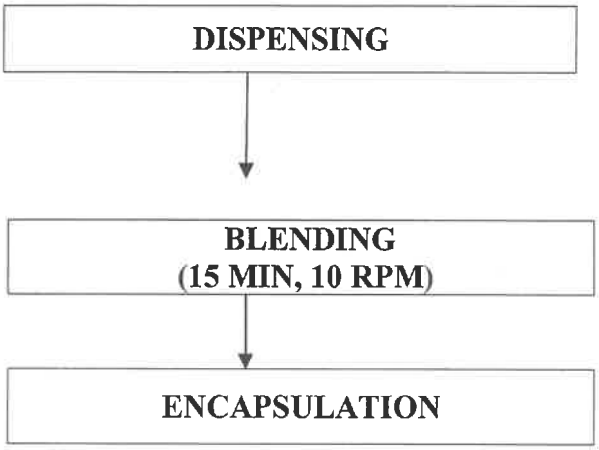
2.0 MANUFACTURING PROCESS FLOW CHART:



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3.0 MASTER FORMULA:

Item Name	Item Code	Specification	Mg/Capsules	UOM	Std. Qty. for (100,000 Capsules)
Lansoprazole (as enteric coated pellets)	GRMA0171	BP	353.000	Kg	35.300
Dummy Pellets	GRME0035	IHS	q.s.	Kg	q.s.
Size "1" Maroon/Maroon	GRME0043	IHS	-	Kg/Nos	7.500/100000

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4.0 CALCULATION :

Qty. of API (Lansoprazole Pellets) required for manufacturing of batch in Kg = X

Label claim of API X Batch size in Nos.

$$X = \frac{\text{.....}}{10,00,000}$$

X =.....

X = ... Kg

If the quantity of API is not sufficient from one AR number then further following calculation shall be done.

Quantity of one AR number available for the batch manufacturing: Y

Remaining quantity required from second AR number: Z

$$Z = \frac{(X - Y) \times \text{Assay of API ODB of First AR Number} \times (100 - \text{LOD of first AR No})}{\text{Assay of API ODB of second AR Number} \times (100 - \text{LOD of second AR No.})}$$

Z = ...

Z = ... Kg

Total quantity required (Y+Z) = ... = ... Kg.

If assay as such is more than 100% then assay to be consider as 100% for calculation.
*value depends on LOD and Assay, to be calculated.
** Value depends upon the compensation.

Done By
Production
Sign & Date:

Checked By
QA
Sign & Date:

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5.0 DISPENSING:

5.1 General Instruction:

To carry out dispensing of Raw material Follow the SOP No.: APD/WAH/003.

5.1.1 Ensure that the relevant documents shall be updated.

5.1.2 Proper line clearance shall be taken before starting the dispensing activity.

5.1.3 All the activities that are related to Equipment Cleaning, Operations, Material Handling and Process Controls, shall be carried out strictly as per respective Standard Operating Procedure.

5.1.4 Check and verify the Item code No., Material, Quantity & A.R. No. of the Material to be dispensed, is as per Material Requisition Slip prior to moving the material in material entry airlock and performing the dispensing activity.

5.1.5 Verify the Raw Material containers for proper close status before and after performing the dispensing activity.

5.1.6 Take raw materials to dispensing area under RLAF.

5.1.7 Start weighing of active ingredients followed by Excipients.

5.1.8 Weigh and dispense all the materials as per dispensing sheet in double polyethylene bags.

5.1.9 Record the material details in dispensing label and affix the label on the dispensed material and same label shall be placed between two poly bags duly approve by Store & QA.

5.1.10 After completion of dispensing activity dispensed material shall transfer in respective production area as per respective SOP.

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5.2 Line Clearance:

To certify the line clearance Follow the SOP No.: **APD/QAD/034.**

Date: _____ **Time:** _____

Previous Product Name: _____ **Batch No.:** _____

S. No.	Check Points	Observation	Checked By Store Sign & Date	Verified By QA Sign & Date
a]	**Area General Checks:**			
1.	Containers/ utensil used for previous batch/product removed from dispensing area	Yes/No		
2.	Containers and vessels in dispensing area shall have cleaned label	Yes/No		
3.	All documents related to the previous batch/ products are removed from dispensing area.	Yes/No		
4.	All previous product/batch remnants removed from area	Yes/No		
5.	Check the Waste bins, it should be clean& empty	Yes/No		
6.	Check gowning of the personnel working in the area, gowning shall be done as per respective area SOP	Yes/No		
7.	Check training records of the personnel working in the area	Yes/No		
b]	**Area Environmental Control checks:**			
8.	Pressure Difference in Dispensing area			
9.	Relative Humidity in Dispensing area			
10.	Temperature of Dispensing area			
11.	Temperature/ humidity log book	Checked/Not checked		
c]	**Area Cleanliness checks:**			
12.	Cleanliness status of floor, corners and walls	Cleaned/ not cleaned		
13.	Area cleanliness record	Checked/not checked		
14.	Area cleaned by			
d]	**General Checks:**			
15.	Cleanliness status of scoops and other accessories	Cleaned/ not cleaned		
16.	Cleanliness status of Balance table.	Cleaned/ not		

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S. No.	Check Points	Observation	Checked By Store Sign & Date	Verified By QA Sign & Date
		cleaned		
e]	**Equipment Checks:**			
Equipment: Balances (UML/WH/G/003)				
17.	Cleanliness status of Balance	Cleaned/ not cleaned		
18.	Daily Weight checking log book of balances	Checked/not checked		
19.	Cleanliness beneath the balance	Cleaned/ not cleaned		
20.	Calibration status of Balance	Calibrated/not calibrated		
Equipment: Balance (APD/WH/G/002)				
21.	Cleanliness status of Balance	Cleaned/ not cleaned		
22.	Daily Weight checking log book of balances	Checked/not checked		
23.	Cleanliness beneath the balance	Cleaned/ not cleaned		
24.	Calibration status of Balance	Calibrated/not calibrated		
25.	Calibration status of Balance	Calibrated/not calibrated		
Equipment: Dispensing Booth (UML/WH/003)				
26.	Cleanliness status of dispensing booth	Cleaned/ not cleaned		
27.	Cleaning log book of Dispensing record	Checked/not checked		
28.	Pressure Difference across HEPA filter in Dispensing Booth (Limit: 8- 20 mm WC)			
29.	Dispensing booth Cleaned by			

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory / not satisfactory. Line clearance given/ not given to proceed with planned process.

Certified by QA (Sign& Date): _____ **Time:** _____

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5.3 Environmental Monitoring:

Dispensing of Raw Material shall be carried out under following Environmental Conditions& Record in Environment Monitoring Record at the time of start of dispensing, after every Four Hours:

Date	Time	Area Name	Temperature NMT 25°C	Relative Humidity NMT 55°C	Differential Pressure 10-20	Checked By Store Sign & Date	Verified By QA Sign & Date

Remarks (If any): _____

5.4 RLAF Monitoring:

Date	Time	RLAF Reading I.D. No.: APD/WH/				Checked By Store Sign & Date	Verified By QA Sign & Date
		Standard Limit Across		Observation			
		MICROVEE Filter	HEPA Filter	MICROVEE Filter	HEPA Filter		
		08-20 mm wc	15-45 mm wc				
		08-20 mm wc	15-45 mm wc				
		08-20 mm wc	15-45mm wc				
		08-20 mm wc	15-45 mm wc				

Remarks (If any):

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5.5 Status Labels of Equipment Cleaning:

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5.6 Dispensing Record:

Dispensing Started On: _____ **Dispensing Completed On:** _____

Item Code	Standard Qty For 1.0 lac Tab. (kg)	Actual Qty For lac Tab. (kg)	UOM	AR No.	Bal. ID No.	Actual weight			Weighed by Warehouse	Checked By Warehouse Sign & Date	Verified By QA Sign & Date
						Gross Wt.	Tare Wt.	Net Wt.			
Lansoprazole Pellets (as enteric coated pellets)											
GRMA 0171	35.300										
Dummy Pellets											
GRME 0035	q.s.										
Maroon/Maroon "1" Size Hard Gelatin empty capsule shell											
GRME 0046	7.500										
Calculation done by (Production)											
Calculation verified by (QA)											

No. Of Packs/Containers: _____

Material Issued By: _____
Warehouse Officer
(Sign & Date)

Material Received By: _____
Production
(Sign & Date)

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5.7 Dispensed Material Verification:

Verify the dispensed Raw Material containers as per Material Requisition Slip after receiving on Production Floor.

S. No.	Material	Specification	AR No.	Gross Weight (kg)	Total Quantity	Checked By Production Sign & Date	Verified By QA Sign & Date
Dry Mixing							
1.	Lansoprazole Pellets (As enteric coated pellets)	BP					
2.	Dummy Pellets	IHS					
EMPTY HARD GELATIN							
3.	Maroon/Maroon Size "1"	IHS					

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6.0 MANUFACTURING RECORD:

6.1 Safety Checklist before Operation of Granulation Area:

Area:_____ **Date:** _____

S. No.	Check Point	Observation	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Check & verify that all jumpers (Continuity cable at flange joint) provided to all inlet and outlet lines are secured.	Complies/Not Complies		
2.	Is any gap between clamp and cover of lighting fixture observed?	Complies/Not Complies		
3.	Is any electrical cable joint observed?	Complies/Not Complies		
4.	Are equipments earthed properly with crocodile clamp?	Complies/Not Complies		
5.	Is **EMERGENCY STOP** switch working (all equipments) can stop instantaneously?	Complies/Not Complies		

Remark (Ifany):_____

_____

___

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6.2 Details of Equipments /Instruments to be used:

Sr. No.	Equipment Name	Equipment Id	Capacity	Reference SOP No.
1.	Octagonal Blender	APD/GT/006	200 Kg	APD/PRD/003
2.	Encapsulation Machine	APD/GC/001,APD/GC/002	NA	APD/ PGT/042

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6.3 Equipments Preventive Maintenance Details:

S. No.	Equipment Name	Equipment ID	Detail of Preventive Maintenance		Checked By Production Sign & Date	Verified By QA Sign & Date	Remarks (If any)
			Done on	Due on			
1.	Octagonal Blender	APD/GT/006					
2.	Encapsulation Machine	APD/GC/001, APD/GC/002					

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6.4 Equipments/Instruments Cleaning Record:

S. No.	Machinery / Equipment	Capacity	Equipments ID No.	Previous Product Name	B. No.	Cleaning Status		Checked By Production Sign & Date	Verified By QA Sign & Date
						Clean On	Done By		
1.	Octagonal Blender	200 kg	APD/GT/006						
2.	Encapsulation Machine	NA	APD/GC/001,APD/GC/002						

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6.5 Status Labels of Equipment Cleaning:

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6.6 Rinse Water Record (Only in case of Product Change Over):

S. No.	Area Name	Previous Product Name	Batch No.	Cleaning Status (OK/Not OK)	Rinse Water A.R No.	*Attached/ Not Attached	Checked By	
							Production Sign &Date	QA Sign &Date
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

*Attach the report of Rinse Water Analysis

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6.7 Line Clearance for Blending area:

Before proceeding to the line clearance, ensure that BMR and other related is updated till last stage of processing.

To certify the line clearance Follow the SOP No.:APD/QAD/034.

Date:_____ **Time:** _____

Previous Product Name: _____ **Batch No.:** _____

S. No.	Check Points	Observation	Checked By Production Sign& Date	Verified By QA Sign& Date
a]	**Area General Checks:**			
1.	Containers / utensil used for previous batch/product removed from area	Yes/No		
2.	Check the gowning of the working personnel's	Yes/No		
3.	Check the training of the working personnel's	Yes/No		
4.	Verify Cleaned status label on all equipments for the batch/ product processing	Yes/No		
5.	All documents related to the previous batch / product is removed from area.	Yes/No		
6.	All previous product/batch remnants removed from area	Yes/No		
7.	Check the Waste bins, it should be clean & Empty	Yes/No		
b]	**Area Environmental Control checks:**			
8.	Pressure Difference in Blending area			
9.	Relative Humidity in Blending area	%		
10.	Temperature in Blending area	°C		
11.	Temperature/Relative humidity log book	Checked /Not checked		
c]	**Area Cleanliness checks:**			
12.	Cleanliness status of floor, corners and walls	Cleaned/ Not Cleaned		
13.	Area cleanliness record	Cleaned/ Not cleaned		
14.	Area cleaned by			

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S. No.	Check Points	Observation	Checked By Production Sign& Date	Verified By QA Sign& Date
d]	**Equipment Checks:**			
Equipment: Octagonal Blender (APD/GT/006)				
15.	Cleanliness status of Blender	Cleaned/ Not cleaned		
16.	Cleanliness status of discharge chute	Cleaned/ Not cleaned		
17.	Cleanliness status of Lid	Cleaned/ Not cleaned		

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory/not satisfactory. Line clearance given/ not given to proceed with planned process.

Certified by QA (Sign & Date): _____ **Time:** _____

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6.8 Dispensed Label to be Paste Here:

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6.9 Blending/Lubrication:

6.9.1 Operate the Blender as per the SOP No. **APD/PRD/003.**

6.9.2 Masks and gloves should be used during operation.

6.9.3 Check for the line clearance, cleanliness of the area and equipment.

6.9.4 Mount blender bin on blender and lock

6.9.5 Operate the blender as per the **SOP:- APD/PRD/003.**

6.9.6 Record the weight of lubricated granules and label the HDPE drum/ bin with product details.

Date:

S. No	Item Name	Quantity kg	Added by into blender	Checked By Production Date& Sign
1	Lansoprazole Pellets			
2	Dummy Pellets			

Date	RPM of Bin blender		Time Start	Time End	Done By	Checked By Production Date & Sign
	Std	Observed				
	10					

6.9.7 After Completion of blending activity transfer the lubricated blend in Double Poly Bag lined HDPE drum/ bin, affix Status and Under Test label as per respective SOP and transfer to Granules quarantine area, weigh and record the details.

6.10 Lubricated Granules Weight:

Drum No.	Clean Status OK/Not ok	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Done By Production	Checked By Production Sign & Date	Remarks (If any)
Total No. of Container		**Total weight**					

Theoretical weight of Blend:

Limit: To be ascertained

Remarks (If Any):

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6.11 Blend Sample Collection Record:

Send Test Request form to QA for sampling.

After sampling, QA shall send the sample along-with intimation to QC for analysis.

Sampling of Lubricated granules shall be performed as per respective SOP.

Intimation No.	Intimated By Production Date & Time	Sampled By QA Date & Time	Quantity Sampled

6.12 Yield Calculation: (Lubricated Blend)

1.	Theoretical weight of blend		**kg**
2.	Actual Weight of blend		Kg
3.	In-process samples		
	A IPQA Samples (if any)	.....kg	
	B QC Samples	.....kg	
	C Validation Samples	.....kg	
4.	Total samples: (A + B + C)		kg
5.	Total: (2 + 4)		kg
6.	Yield {(5/1) x 100} = _____ X 100 **(Record the yield)**		_____ % **Limit: To be ascertain**

Remarks (If Any):

_____

Done By Production (Sign & Date) | **Checked By Production (Sign & Date)** | **Verified By QA (Sign & Date)**

6.13 Blend Release Record:

(To be filled by QA Officer /Executive)

Date of Release: _____ Sample Intimation No.: _____

AR No.: _____ Result: **Complies / Does not Complies**

Test Report attached/Not Attached

Checked By QA
(Sign & Date) _____

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7.0 Encapsulation:

7.1 General Instruction:

7.1.1 Gowning should be as per respective SOP.

7.1.2 Check for the line clearance, Cleanliness status of the area and equipment.

7.1.3 After receiving release of lubricated granules from Quality Assurance, proceed for the Encapsulation.

7.1.4 Carry out the Initial Checks of Encapsulation Machine setting.

7.1.5 Mask and gloves should be used throughout Encapsulation.

7.1.6 Counter check weights of total finished granules.

7.1.7 Set the dies, tools & operate the Encapsulation machine, as per Respective SOP.

7.1.8 In case if Encapsulation activity is carried out on next day i.e. process is started after shutdown; additional pages for encapsulation activity (Including Safety Checklist, Line clearance, Environmental Monitoring of Encapsulation Area, Encapsulation Machine Tool Verification, Encapsulation Parameters Start Up & In-process, Encapsulation Operation Details.

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7.2 Safety Checklist (Before Operation of Encapsulation Machine):

Area:_____ **Equipment ID No:**_____ **Date:** _____

S. No.	Check Point	Observation	Checked By Production Date& Sign	Verified By QA Date& Sign
1.	Does the Door interlocks (limit switches) working properly?	Complies/Not Complies		
2.	Are all required Personnel Protective Equipments available?	Complies/Not Complies		
3.	Are Electrical cables in good condition and free from joints?	Complies/Not Complies		
4.	Is **EMERGENCY STOP** switch working (Encapsulation machine) can stop instantaneously?	Complies/Not Complies		

Remarks (If Any):

7.3 Line Clearance:

To certify the line clearance Follow the SOP No.: **APD/QAD/034.**

Date: _____ **Time:** _____

Previous Product Name: _____ **Batch No.:** _____

S. No.	Check Points	Observation	Checked By	
			Production	QA
a]	**Area General Checks:**			
1.	Containers/ Utensil materials used for previous batch/product removed from area	Yes/No		
2.	Cleaned status label on all equipments for the batch/product	Yes/No		
3.	All documents related to the previous batch / products are removed from area.	Yes/No		
4.	BMR till last processed stage is updated	Yes/No		
5.	All previous product/batch remnants removed from area	Yes/No		
6.	Check the Waste bins; it should be clean & empty.	Yes/No		
b]	**Area Environmental Control Checks:**			
7.	Pressure Difference in Encapsulation area (Limit: NLT 08 Pascal/Kg/cm^2)			
8.	Relative Humidity in Encapsulation area (Limit: NMT 55%)			
9.	Temperature of Encapsulation area (Limit: NMT 25°C)			
10.	Temperature/Relative humidity log book	Checked/ Not checked		
c]	**Area Cleanliness checks:**			

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S. No.	Check Points	Observation	Checked By	
			Production	QA
11.	Cleanliness status of floor, corners and walls	Cleaned/ Not cleaned		
12.	Area cleanliness record	Cleaned/ Not cleaned		
13.	Area cleaned by			
d]	**Equipment No.: Encapsulation Machine APD/**			
14.	Cleanliness status of Magazine assembly	Cleaned/ Not cleaned		
15.	Cleanliness status of Hopper assembly	Cleaned/ Not cleaned		
16.	Cleanliness status of powder assembly	Cleaned/ Not cleaned		
17.	Cleanliness status of sorter assembly	Cleaned/ Not cleaned		
18.	Cleanliness status of polishing assembly	Ok/Not ok		
19.	Calibration status of	Ok/Not ok		
e]	**Misc. Equipments:**			
20.	Calibration status of Vernier Caliper	Calibrated/not calibrated		
21.	Calibration status of Disintegration Apparatus	Calibrated/not calibrated		

LINE CLEARANCE CERTIFICATE:

Observations of Area, Equipment and Environmental checks are found satisfactory/ not satisfactory. Line clearance given/ not given to proceed with planned process.

Certified by QA (Sign& Date): _____ **Time:** _____

7.4 Environmental Monitoring of Encapsulation Area:

Check and record the Temperature, Humidity and pressure difference as per respective SOP.

Frequency: At the start of operation and thereafter every four hours.

Date	Time	Room Name	Temp. NMT 25°C	Relative Humidity NMT 55%	Differential Pressure NLT 08 Pascal/Kg/cm²	Checked By Production Date& Sign	Verified By QA Date& Sign

Remarks (If Any):

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7.5 Encapsulation Machine Tool Verification:

Date: _____ **Time:** _____

Parameters	Specification	Frequency	
		Production	QA
Capsule Size	# 1		
Appearance	Capsules, Brown/Brown Size "1"	Initially check	Initially check
Average weight of a Empty Capsule	75.000 mg	Initially check	Initially check
Weight of 20 Empty Capsule	1.500 gm ± 2% (1.470 g to 1.530 g)	Initially check	Initially check
Net content of a Capsule	355 mg ± 7.5 % (328.375 mg to 381.625 mg)	Initially check	Initially check
Average wt of a Capsule	430.000 mg ± 7.5 % (397.75 mg to 462.25 mg)	Initially check	Initially check
Weight of 20 Capsule	8.600 gm ± 2 % (8.428 gm to 8.772 gm)	Initially & Every 1 hr	Initially & Every 2 hr
Locking length	NMT 20 mm ±0.5 mm	Initially & Every 1 hr	Initially & Every 2 hr
Disintegration Time	NMT 30 Min.		
Temperature of area	NMT 25°C	Initially & After Every 3 hr	Initially & After Every 3 hr
Relative humidity	NMT 55 %		
Pressure Differential	(NLT 08 Pascal)		

7.6 Encapsulation Operation Details:

Date	Encapsulation Started at	Encapsulation Completed at	Operated By	Checked By Production Sign & Date
Total Time:				

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7.7 INITIAL CHECKS:

7.7.1 Verification of Initial Settings of Capsule filling Machine :

Process Parameter	Limit	Observation
Appearance:	Size 1 capsules, Brown/Brown	
Weight of 20 Capsule	8.600 gm ± 2 % (8.428 gm to 8.772 gm)	

7.8 INDIVIDUAL WEIGHT OF 20 CAPSULE

Sr. No.	Individual wt. of Filled Capsule 430.00 mg ± 7.5 % (397.75 mg to 462.25 mg)	Net content of a Capsule 355 mg ± 7.5 % (328.375 mg to 381.625 mg)	Average weight of Empty Capsule 75.00 mg ± 5.0 % (71.25 mg to 78.75 mg)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

Done By (Prod.)
Sign & Date: _____

Verified By (QA)
Sign & Date: _____

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7.9 In- process check Sheet for Production :

Date	Time	Every 1 hr	Every 3 hr				Done By (Prod) Sign & Date
		Wt. of 20 caps 8.600gm±2%(8.428gm to 8.772gm)	DT (NMT 30 Min)	Locking length(NMT 20 mm)	Temp. (° C) NMT 25°C	RH % NMT 55 %	

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7.10 Individual Weight Verification sheet for QA :

Date	Time	Every 1 hr	Every 3 hr				Done By (QA) Sign & Date
		Wt. of 20 caps 8.600gm±2%(8.428 gm to 8.772gm)	DT (NMT 30Min)	Locking length (NMT 20 mm)	Temp. (° C) NMT 25°C	RH % NMT 55 %	

Generic Name: Gastro-Resistant Lansoprazole Capsules BP	
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7.11 Filled Capsule Weight:

7.11.1 Verify the Balance Calibration Status prior to weighing:

Balance ID	Capacity	Calibration Status (Ok/ Not Ok)	Checked By Production Sign & Date	Verified By QA Sign & Date

7.11.2 Weighing Record:

Container No.	Clean status Ok/Not Ok	Gross Wt. (Kg)	Tare Wt. (Kg)	Net Wt. (Kg)	Remarks (If any)
Total No. of Container			Total weight		

Theoretical weight of Filled capsule: .

Limit: To be ascertained

Done By Production: _____
(Sign & Date)

Checked By Production _____
(Sign & Date)

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7.12 Reconciliation of Filled Capsule :

Sr.No.	Calculation Points	Observed Values	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Weight of Filled Capsule (Kg) (A)			
2.	Theoretical Batch size (Kg) (B)			
3.	In Process Sample			
4.	QC Sample			
5.	Validation Sample			
6.	Total Sample (D)=(3+4+5)			
7.	Actual Yield [(A/B+D) x100]			
8.	Non Recoverable (Kg)			

7.13 Sampling, Analysis and Release of Filled Capsule

Send the intimation slip to QA Dept. to draw the sample of Capsule for analysis as per SOP No.: .....

Sampling, Analysis Details:

Intimated By Production Sign & Date	Intimation Received By QA Sign & Date	Sampled By QA Sign & Date	Quantity Sampled

The Filled capsules are **Released/ Not Released** for Inspection/ Packing.

QA Sign & Date: _____ **Time:** _____

Attach the Report from QC: _____ **A.R. No:** _____

7.14 Transfer above Filled Capsule to quarantine.

Date of Transfer	Qty. Transferred (in kg)	Transferred By Sign & Date	Verified By QA Sign & Date

7.15Issuance of Filled Capsule to Inspection:

Date of Issue	Qty. Issued (in kg)	Issued By Sign & Date	Verified By QA Sign & Date

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8.0 Inspection of Capsule

Line Clearance

Area :.....Line clearance checked at .....on.....

Previous Product:.....B. No.....

If the previous product same ensure that the powder of earlier batch is completely removed

S. No.	Particulars	Remark (Yes/No)	Done By	Checked By Prod.	Verified By QA
1.	Cleanliness of Area				
2.	Cleanliness of Inspection belt				
3.	Status Label of previous product				
4.	Container of previous product				
5.	Tablet of previous product				
Temperature of area (NMT 25°C)		°C			
RH of area (NMT 55%)		%			

Checked By Production Sign/Date..... Verified By QA Sign/Date .....

Capsule Verification:

Date	Time		Weight of Capsule taken for Checking (kg)	Weight of good Capsule (kg)	Weight of recoverable residues (kg)	Weight of non-recoverable residues (kg)	Done by	Ckd. by
	From	To						

Weight Verification:

Date	Container No.	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Checked by	
					Prod.	QA

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Total weight						

Finished Tablet Release:

Finished Tablet Release report attached here.

Report No. ……..

Checked By Production Sign/Date……. Verified By QA Sign/Date ……..

9.0 Destruction of Non Recoverable: Carry out Destruction as per respective SOP.

Stage	Non Recoverable Qty.(kg)	Qty. Destroyed (kg)	Destroyed By Sign& Date
Blending/Lubrication			
Encapsulation			
Inspection			

Destroyed in presence of QA
Sign & Date: _____

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10.0 SIGNATURE LOG:

S. No.	Name of the Employee	Employee Code	Department	Spécimen Signature

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11.0 INCIDENT/DEVIATION RECEIVED (If Any):

Incident No.:

Deviation No:

Status: _____

Checked By QA:
Sign & Date: _____

12.0 BREAK DOWN DETAILS:

Date	From	To	Nature of Break Down	Area	Stage	Break Down Time	Rectification Time

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13.0 BATCH MANUFACTURING HISTORY SHEET:

S. No.	Stage	Start Date	End Date	Checked By Production Sign & Date	Verified By QA Sign & Date
1.	Dispensing				
2.	Manufacturing				
3.	Encapsulation				
4.	Inspection				

14.0 CHECK LIST FOR BATCH MANUFACTURING RECORDS & RELEASE FOR PACKING:

S. No.	Check Points	Status
1.	All the pages are available and comply with index.	Yes / No
2.	Batch number available in all pages.	Yes / No
3.	Manufacturing and expiry date is correctly quoted.	Yes / No
4.	Dispensing carried out on calibrated balance.	Yes / No
5.	Line Clarence is taken prior to all dispensing, Blending Area, Encapsulation area activity.	Yes / No
6.	Dispensing is carried out as per Bill of materials.	Yes / No
7.	The entire dispensed label is properly affixed.	Yes / No
8.	Environmental condition complies during all the manufacturing steps.	Yes / No
9.	No overwriting are observed all wrong entries are having been strike out and signed.	Yes / No
10.	Actual equipments are used as specified.	Yes / No
11.	Batch dispensing is carried out after QA approval.	Yes / No
12.	Batch manufacturing is carried out after QA approval.	Yes / No
13.	Batch Encapsulation is carried out after QA approval.	Yes / No
14.	QC approval is available on test request form	Yes / No
15.	Yield and reconciliation of all stage is within acceptance limit.	Yes / No
16.	All the in process check result comply within the acceptance limit	Yes / No
17.	All the blank space is filled correctly without pending entries.	Yes / No
18.	Batch reconciliation is completed and complies within the limit (In case it is outside limit justification is available)	Yes / No
19.	If there is any deviation during the in process, it is recorded in process History sheet and deviation is raised and approved.	Yes / No
20.	Status Labels of Machinery	Yes / No
21.	TR of wash water, blend and TR of filled capsules attached.	Yes / No
22.	RM excess issue order (if applicable)	Yes / No
23.	Deviation and its Justification	Yes / No
24.	Signature of Authorized Persons	Yes / No
25.	Legibility of contents	Yes / No

BMR Checked By:
Production (Sign & Date)

BMR Reviewed By:
QA (Sign & Date)

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15.0 QC Data review Checklist:

S. No.	Check points	Status
1.	Analytical report complete and approved	Yes / No
2.	Records are readable, unequivocal & correct	Yes / No
3.	Test according to current authorized specification and standard test procedure	Yes / No
4.	Test results are according to approved specification	Yes / No
5.	All raw data along with signed copy of audit Trail	Yes / No

Reviewed By QA/QC
Sign & Date:

16.0 ABBREVIATION:

%	: Percentage
#	: Mesh
°C	: Degree Centigrade
&	: And
Approx.	: Approximately
A.R.	: Analytical Report
Avg.	: Average
B. No.	: Batch Number
Bal.	: Balance
BMR	: Batch Manufacturing Record
Ckd.	: Checked
Dt.	: Date
Exp.	: Expiry
Gm/g	: Gram
GMP	: Good Manufacturing Practice
IP	: Indian Pharmacopoeia
kg	: kilogram
L	: Liter
L.A.	: Labeled Amount
L.C.	: Label Claim
LOD	: Loss on Drying
Mfg.	: Manufacturing
mg	: Milligram
min	: Minutes
Kg/cm^2	: Kilogram per centimeter square
mm	: Millimeter
mm	: Millimeter
NA	: Not Applicable
NLT	: Not Less Than
NMT	: Not More Than
No. / Nos.	: Number / Numbers

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Prod.	: Production
QA	: Quality Assurance
QC	: Quality Control
Qty.	: Quantity
q.s.	: Quantity Sufficient
Ref.	: Reference
RH	: Relative Humidity
RMG	: Rapid Mixer Granulator
RPM	: Rotation Per Minute
R.O.	: Role on
Sr. No.	: Serial Number
SOP	: Standard Operating Procedure
S.S	: Stainless Steel
Temp.	: Temperature
Wt.	: Weight
w/w	: Weight by Weight
±	: Pluses and Minus
DT	:Disintegration Test
TR	: Test Report

17.0 DOCUMENT REVISION HISTORY:

Revision No.	Effective Date	Details of Revision	Reason For Revision	Change Control No.
00	26/02/2024	NEW BMR	New BMR	NA