	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:**	
Document No.:	**Effective Date:**	**Page No.:** 1 of 22
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets (PT)	
Label Claim:	Each uncoated tablet contains: Amlodipine Besilate IP Eq. to Amlodipine …….. 2.5 mg Excipients ……q.s. Colour: Tartazine
Mfg. Lic. No.:	
Product Lic. No.:	NA
Self-Life:	24 months
MFR No.:	
Mfg. Date:	
Exp. Date:	
BMR ISSUED No.:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 2 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

1.0 MASTER FORMULA:

BILL OF RAW MATERIALS

Sr. No	Ingredients	Spec.	Qty. In mg Per Tablet	Overages %	Batch Qty. In Kg
Raw Material for Dry Mixing					
Active Ingredients-					
1.	Amlodipine Besylate	IP	3.625 eq. to 2.5 mg	----	0.725#
Inactive Ingredients-					
2.	Microcrystalline Cellulose (MCCP)	IP	65.276	-----	13.06
3.	Starch	IP	32.275	-----	6.45
4.	Colour Tartrazine Yellow Supra	IP	0.3	------	0.06
Raw Material for Binder Preparation-					
5.	ISO Propyl Alcohol	IP	50	---	10.00
6.	PVPK-30	IP	3.333	----	0.66
Raw Material for Lubrication-					
7.	Collidal Silicon Dioxide	IP	1.3	----	0.26
8.	Talcum Powder	IP	2	----	0.40
9.	Sodium Bicarbonate	IP	2	-----	0.40
10.	Sodium Luryl Sulphate	IP	1	------	0.20
11.	Sodium Starch Glycolate	IP	2.2	------	0.44
12.	Magnesium Stearate	IP	2	-----	0.40
Weight of Uncoated Tablets			**115 mg**		**23.05 Kg**

Note: # Amlodipine Besylate IP add after calculation.

	Prepared By	Checked By	Approved By
Signature			
Date			

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Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

CALCULATION SHEET

1- Amlodipine Besylate IP is to be taken as per the formula given below:

Note: If assay of API is above 99.0% calculation not required.

Part A: To be calculated when single AR No.:
Assay on dried basis: _____ LOD: _____

PART A: To be Calculated when single A.R. No of **Amlodipine Besylate IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

Assay on as such basis = $\frac{(100\text{-LOD}) \times \text{Assay on dried basis}}{100}$ = _____%

A.R. No. **of Amlodipine Besylate IP**	Assay on as such basis **(A1)**	Actual quantity of this A.R. No. to be dispensed =
	----------%	$\frac{0.725\# \times 100}{A1}$ = ----------Kg

PART B: To be Calculated when more than one A.R. No's of **Amlodipine Besylate IP** is to be used:

A.R. No. of **Amlodipine Besylate IP**	Assay on as such basis (A1)	Actual quantity Available (b1) (Kg)	Qty. on 100 % assay basis = $\frac{(b1) \times (a1)}{100}$ kg	Remaining qty. to be dispensed (e1) = Std. qty. -(d1)
				(e1) = 0.725# -_ = kg
TOTAL (Kg) ---		_____	(c1)=_____	

Assay of next AR No. ---------- (Assay on as such basis) (f1) = _____%

Actual quantity of this AR No. to be dispensed (g1) = $\frac{(e1) \times 100}{(f1)}$ =----------Kg

Therefore total quantity of **Amlodipine Besylate IP** to be dispensed = (c1) + (g1) =_____Kg

Assay calculation:

Sign/ Date		
Department	**Done by(Production)**	**Checked by (Q.A.)**

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

2.0 GENERAL INSTRUCTIONS:

- Current version of SOPs should be referred during operation.
- Dispensed raw material/bulk blend/ compressed tablets should be manufactured and stored at temperature not exceeding 25°C and RH NMT 55%
- In all the processing activities, nose mask, hand gloves, secondary gown etc. shall be wearied by the personnel.
- Attach all dispensing tags and cleaning status labels with BMR.
- Clean the equipment's after use as per the standard operating procedure.
- The Blend should be compressed within 15 days.
- The compressed tablets should be packed within 30days.

2.1 Line clearance of Dispensing:

Check the instructions given below and note the observation as Yes, NO or NA.

Sr. No.	Instructions	Yes/No/NA
1.	Is dispensing area clean and free from any materials of previous batches?	
2.	Whether balance is calibrated and have status label.	
3.	Scoops to be used for dispensing are clean.	
4.	LAF properly working and dispensing booth clean.	
5.	Air differential pressure, temperature and humidity with in limit (if applicable) Temp. ---------- ºC(NMT 25ºC), RH----------% (NMT 55.0%), DP……..(5to15P or in mm of H_2O)	
6.	Material shall be least exposed to atmosphere.	
7.	Ensure proper gowning before entering to the dispensing area, suitable nose mask and surgical gloves shall be used while handling the material.	

Previous product name:		**Batch No.:**	
Differential pressure across RLAF and Room:		(Limit(Between 5 to 15 Pascal)	
Checked By (Production): **Sign & Date:**		**Verified By(IPQA):** **Sign & Date:**	

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 5 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

BILL OF RAW MATERIALS **(PRODUCTION COPY)**

Sr. No.	Ingredients	Batch Qty. In Kg	Actual Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
					Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-										
Active Ingredients-										
1.	Amlodipine Besylate IP	0.725#								
Inactive Ingredients-										
2.	Microcrystalline Cellulose (MCCP) IP	13.06								
3.	Starch IP	6.45								
4.	Colour Tartrazine Yellow Supra IP	0.06								
Raw Material for Binder Preparation-										
5.	ISO Propyl Alcohol IP	10.00								
6.	PVPK-30 IP	0.66								
Raw Material for Lubrication-										
7.	Collidal Silicon Dioxide IP	0.26								
8.	Talcum Powder IP	0.40								
9.	Sodium Bicarbonate IP	0.40								
10.	Sodium Luryl Sulphate IP	0.20								
11.	Sodium Starch Glycolate IP	0.44								
12.	Magnesium Stearate IP	0.40								

Note: # Amlodipine Besylate IP add after calculation.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
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Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

BILL OF RAW MATERIALS **(STORE COPY)**

Sr. No.	Ingredients	Batch Qty. In Kg	Actual Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
					Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-										
Active Ingredients-										
1.	Amlodipine Besylate IP	0.725#								
Inactive Ingredients-										
2.	Microcrystalline Cellulose (MCCP) IP	13.06								
3.	Starch IP	6.45								
4.	Colour Tartrazine Yellow Supra IP	0.06								
Raw Material for Binder Preparation-										
5.	ISO Propyl Alcohol IP	10.00								
6.	PVPK-30 IP	0.66								
Raw Material for Lubrication-										
7.	Collidal Silicon Dioxide IP	0.26								
8.	Talcum Powder IP	0.40								
9.	Sodium Bicarbonate IP	0.40								
10.	Sodium Luryl Sulphate IP	0.20								
11.	Sodium Starch Glycolate IP	0.44								
12.	Magnesium Stearate IP	0.40								

Note: # Amlodipine Besylate IP add after calculation.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

2.2 Weighing sheet:

Balance ID: _____

Sr. No.	Ingredients	Spec.	UOM	Std. Quantity (kg)	A.R No.	Issued Qty			Checked By (Production)	Verified by (IPQA)
						Tare wt.	Net wt.	Gr. Wt		
MATERIAL FOR GRANULATION:										
1.	Amlodipine Besylate	IP								
2.	Microcrystalline Cellulose (MCCP)	IP								
3.	Starch	IP								
4.	Colour Tetrazine Yellow	IP								
5.	PVPK-30	IP								
MATERIAL FOR LUBRICATION:										
1.	Collidal Silicon Dioxide	IP								
2.	Talcum	IP								
3.	Sodium Bicarbonate	IP								
4.	Sodium Lurly Sulphate	IP								
5.	Sodium Starch Glycolate	IP								
6.	Magnesium Stearate	IP								

3.0 GRANULATION PROCESS: **Granulation started on:**_____

3.1 Line clearance of Granulation:

Previous product: _____, **Batch No.:**_____

Cleaning done by: _____, **Cleaned On:** _____,

Sr. No.	Instructions	Yes/No/NA	Checked By (Production)	Verified By (IPQA)
1	Ensure that all equipment and utensils are clean and dry and status board affixes (Record as per Table-1).			
2	Is area free from any materials of previous batch?			
3	Whether the container, sieve, scoops and auxiliary items are cleaned.			
4	Check the room temperature. Temp……..ºC (NMT 25ºC) and Differential pressure ……. Pascal (5to 15 Pascal or in mm of H_2O).			
5	AHU system under operation or not.			
6	Calibration status of Equipment/instrument complies or not.			
7	Balance calibration status is OK or not.			
8	Whether swab/rinse sample testing report complies or not? (if applicable)			
9	Whether the wall, floor and light in satisfactory condition?			

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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

EQUIPMENT STATUS CHECKLIST

Sr. No.	Name of Equipment	Equipment ID No.	Observation (Should be clean and dried)	Checked (Production)	Verified By (IPQA)
1.	Shifter		Yes/No		
2.	Rapid granulation mixture(RMG)		Yes/No		
3.	Paste kettle		Yes/No		
4.	Full bed drying (FBD)		Yes/No		
5.	Multimill		Yes/No		
6.	Octagonal blender		Yes/No		
7.	Balance		Yes/No		
8.	SS scoop		Yes/No		

3.2 Sifting: Sift separately the following material and collect in poly bags/containers. Check sieve integrity before and after use.

SIFTING OF GRANULATION MATERIALS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd. By/ Date
			Before Use	After use				
Amlodipine Besylate								
Microcrystalline Cellulose (MCCP)								
Starch								
Colour Tetrazine Yellow								
PVPK-30								

SIFTING OF BLENDING MATERIAL / LUBRICANTS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd By/ Date
			Before Use	After use				
Collidal Silicon Dioxide								
Talcum								
Sodium Bicarbonate								
Sodium Lurly Sulphate								
Sodium Starch Glycolate								
Magnesium Stearate								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

3.3 MANUFACTURING PROCESS:

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Binder preparation:**					
	Prepare paste by taking **10 Lts**. of **Iso Propyl Alcohol** in SS container add **0.66 Kg PVPK-30** and dissolved completely.					
3.3.2	**Dry Mixing:**					
	Add **Amlodipine Besylate** (____Kg)**, Starch** (6.45 Kg)**, Microcrystalline Cellulose** (13.06 Kg)**, and Colour Tartrazine Yellow** (0.06 Kg) **i**n SS Container and mixed properly.					
3.3.3	**Wet granulation:**					
	Add the binder paste in Step- 3.3.2 after complete addition of total quantity of binder solution, mixed the materials properly.					
3.3.4	**Drying:**					
	Dry the granules at ___°C to ___°C temperature.					
	Collect the granules from 5 different places of the bowl and check loss on drying.					
	LOD. _____%w/w. Recommended LOD: (NMT _____ % w/w)					
3.3.5	**Sizing /Milling :**					
	Sift the dried granules through Vibratory sifter fitted with16# Sieve.					
	Before Use	**After Use**				
	Rusted : Yes / No	Rusted : Yes / No				
	Broken : Yes / No	Broken : Yes / No				
	Clean : Yes / No	Clean : Yes / No				
	Mill the oversize granules retained on sieve of vibratory sifter using multimill fitted with **_____mm** screen. With knife forward direction at medium speed.					
	Before Use	**After Use**				
	Rusted : Yes / No	Rusted : Yes / No				
	Broken : Yes / No	Broken : Yes / No				
	Clean : Yes / No	Clean : Yes / No				
3.3.6	**Blending & Lubrication:**					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Document No.:	**Effective Date:**	**Page No.:** 10 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
	Take SS Container add **Collidal Silicon Dioxide IP** 0.26Kg, **Talcum IP** 0.40Kg, **Sodium Bicarbonate IP** 0.40 Kg , **Sodium Luryl Sulphate IP** 0.20 Kg & **Sodium Starch Glycolate IP** 0.44 Kg and dried granules and mix it properly.					
3.37	Add **Magnesium Stearate IP** 0.40 Kg in Step-3.3.6 and mix for further for 5 minutes.					

GRANULE WEIGHING RECORD

Container No.	Tare wt. (Kg)	Gross wt. (Kg)	Net wt. (Kg)	Done By/ Date	Ckd By/ Date
1/					
2/					
3/					
4/					
5/					
6/					
7/					
8/					
9/					
10/					
Total					

4.0 YIELD RECONCILIATION:

A = Theoretical batch size = …….. Kg / ……... tablets

B = Actual quantity of blend = …….. Kg

C = Samples = ….. ……..

D = Yield = B / A x100 **(Note: - Granulation yield NLT 99.00%)**

Loss Quantity: _____

Checked by (Production):
Date:

Verified by (QA):
Date:

	Prepared By	Checked By	Approved By
Signature			
Date			

4.1 SAMPLING OF BLEND:

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of granulation process.

_____
Checked By (Production)

- IPQA shall review batch card and visually inspect of the material for physical Appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Checked By (IPQA)

- After release from QC, IPQA shall paste the 'APPROVED" label on each container.

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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

5.0 COMPRESSION:

Date: _____ **Started At: _____**

5.1 Line clearance:

Previous product: _____, Batch No.:_____

Sr. No.	Instructions	Observations	Checked (Production)	Verified By (IPQA)
1	Is area free from any materials of previous batch?	Yes/No		
2	Whether area and utensils cleaned?	Yes/No		
3	Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? Equipment ID No.: _____	Yes/No		
4	Check the room temperature, RH and differential pressure =……ºC (NMT 25ºC), RH=…… % (NMT 55%). Differential Pressure……..mm of H_2O(0.5to 1.5 mm of H_2O)	OK/NOT OK		
5	All the equipment shall be used during process are cleaned.	Yes/No		

5.2 Process:

	Compression Instruction	Observations	Checked (Production)	Verified By (IPQA)
5.2.1	Collect the approved granules from the granules store for compression.			
5.2.2	Ensure the correct punch set is assembled in the compression machine.			
5.2.3	Ensure the availability and online filling of Batch Document.			
5.2.4	Collect the tablets as per total no. of punches from each side and check them individually for any damages on upper and Lower Surface before continuing the operation of compression machine. Check and Record the observation and details of die & punch in the table A: **Die and punch verification**			
5.2.5	If compression time is less than one hour , minimum Three observations shall be recorded.			
5.2.6	Ensure that all the data of actual processing are entered in log book of individual equipment/Instrument.			
5.2.7	Collect the compressed tablets in polythene lined container. Weight the containers and record the weights in table given below, label them properly and transfer them to bulk store (Container number should be given as 1/x, 2/x…… where x is the total number of containers			

	Prepared By	Checked By	Approved By
Signature			
Date			

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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

Table: A-Die and punch verification

Punch Specification																								
Punch Details	Type	Prism: ____ Tooling _____ Stations.																						
	Upper Punches	6.3 mm (Round with break line)																					Dies : 6.4 mm	
	Lower Punches	6.3 mm (Round plain)																						
Upper Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											
Lower Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											

Checked by (Production):_____ **Verified By (IPQA):_____**

5.3 IN PROCESS CHECKS:

5.3.1 Specification:

Sr. No.	Parameters	Requirement	Frequency of Monitoring
1.0	Description	Round shape biconvex tablets with one side break line.	At the start of machine
2.0	Weight of 20 tablets	2.30gm± 3%	Every 30 Minutes
3.0	Avg. weight	115 mg ± 7.5%	Every 2 Hours
4.0	Uniformity of weight	115 mg ± 7.5%	Every 2 Hours
5.0	Thickness	2.9 ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3.0 Kg/cm^2	Every 2 Hours
7.0	Friability	NMT 1%	Every 2 Hours
8.0	DT	NMT 15 min	Every 2 Hours
9.0	Diameter	6.3 mm ± 0.2mm	At the start of machine
10.0	Appearance	Yellow colour round shape biconvex tablets with one side break line	Every 2 Hours
11.0	Temperature	NMT 25 ° C	Every 2 Hours
12.0	RH	NMT 55%	Every 2 Hours

	Prepared By	Checked By	Approved By
Signature			
Date			

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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

5.4 In-process observation sheet for production:

Description:											
Diameter of tablets:											
Wt. of 20 Tabs. **2.30gm± 3%**	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. **2.30gm± 3%**	**Date**										
	Time										
	LHS										
	RHS										
Thickness **2.90 ± 0.2 mm**	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: Yellow colour round shape tablets with one side break line	LHS										
	RHS										
Temperature (NMT 25°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required…

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

Average Weight of Tablet:		**Frequency**	**Every 2 hours.**

Date:								
Time:								
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
Avg. Wt.								
Min wt.								
Max wt.								
Checked by								

Attached additional sheet if required…….

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

5.5 In-process observation sheet for IPQA:

Description:											
Diameter:											
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 2.9 ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: Yellow colour round shape tablets with one side break line	LHS										
	RHS										
Temperature (NMT 25°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required……..

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

WEIGHT VARIATION OF 20 TABLETS

Average Weight of Tablet:		**Frequency**	**Every 2 hours.**

Date:								
Time:								
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
Avg. Wt.								
Min wt.								
Max wt.								
Checked by								

Attached additional sheet if required……..

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 18 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

3.0 TABLET WEIGHING RECORD:

Container No.	Tare wt.	Gr. Wt.	Net wt.	Container No.	Tare wt.	Gr. Wt.	Net wt.
1/				**11/**			
2/				**12/**			
3/				**13/**			
4/				**14/**			
5/				**15/**			
6/				**16/**			
7/				**17/**			
8/				**18/**			
9/				**19/**			
10/				**20/**			
Total net weight of Tablets:							
Checked By(sign & Date):							

4.0 YIELD RECONCILIATION:

•	Average weight of tablets (A)=: mg
•	Total weight of compressed tablets (B) = Kg.
•	Quantity of compressed tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
•	Samples (D)=
•	Yield= $\frac{C + D}{\text{Actual batch size}}$ x 100= **(Yield NLT: 98.50%)**

Checked By (Production):	**Verified By (IPQA):**

Loss Qty.: _____ Kg.

5.0 SAMPLING :

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
Checked By (Production)

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Checked By (IPQA)

- After release from QC IPQA shall paste the **'APPROVED"** label on each drum.

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 19 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

6.0 COATING: **Date:**_____

6.1 Line clearance:

Previous product: _____, **Batch No.:**_____

Sr. No.	Instructions	Observations	Checked By	
			Production	QA
1	Ensure that Colloid mill, SS Tank, 100# sieve, coating pan, Spray gun and scoop are cleaned.	Yes/NA/NO		
2	Is area free from any materials of previous batch?	Yes/NA/NO		
3	Whether the scoops and auxiliary items are cleaned.	Yes/NA/NO		
4	Check the room temperature. Temp……..ºC (NMT 25ºC). & RH ……% (NMT 55%)	-		
5	Whether the Auxiliary items are cleaned.	Yes/NA/NO		
6	Whether the coating pan is cleaned and set as per SOP and have "CLEANED" label affixed.	Yes/NA/NO		
7	Balance calibration status is OK or not.	Yes/NA/NO		
8	Whether tablet approved or not?	Yes/NA/NO		
Differential pressure across RLAF and Room:		(Limit (Between 5to15 Pascal)		
Checked By:(Production):		Verified By:(IP/QA)		
Sign and Date:		Sign and Date:		

7.0 COATING PROCESS:

Equipment ID to be used: _____ _____, Coating started on: _____

	Instructions	Std. time (min)	Observed time		Done By) (Sign & Date)	Checked By (Sign & Date)	Remarks
			From	To			
Solution preparation	Pass the solution in homogenizer to uniform suspension to avoid inclusion of air bubbles. Filter the suspension through 200 # muslin cloth cover the prepared suspension in the vessel securely for use before coating.	-					
	Keep aside with lid cover. Ensure Coating solution should be free from air bubbles.	-					
	Cover the prepared solution in the vessel securely for use before coating with labels affixed on vessel mentioning batch details.						
Coating of Tablet	Take sorted tablet in coating room	-					
	Fit the spray gun with 1.5mm diameter nozzle and set the atomizing air pressure at 2.5-4.0 kg/cm2. Start the exhaust system.	-					
	Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM2-3) and pre warm the tabs to obtain the bed temperature (42 to 48ºC).	-					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 20 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

	Start the spraying solution over the tablet and let them be dry immediately.	-					
	After drying unload the coating tablets in pre-tare Polybag lined drum with status label.	-					
	Check and record the physical parameters of coated tablets as per given check sheet.	-					

8.0 COATING INPROCESS CHECKS: (Record the observation every half an hour)

Lot-I

Parameter	**Limit**	**Date**						
		Time						
Pan Speed	4 to 5 RPM							
Inlet Air Temperature	65to 75^0 C							
Peristaltic Pump Speed	16 RPM							
Atomizing Air Pressure	2.5 to 4.0kg/cm2							
Exhaust Air Temperature	42 to 48 ^{0} **C**							

PARAMETERS AFTER COATING: **Lot-I**

Tests	**Specification**	**Production observation**	**IPQA observation**
Description	Yellow colour round shape tablets.		
Weight of 20 tablets	_____		
Avg. weight	_____		
Uniformity of weight	_____		
Thickness	_____ mm		
Disintegration	NMT 30 Minutes		
Checked by (Production):		**Checked By (IPQA):**	

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 21 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

8.1 WEIGHING RECORD OF COATED TABLETS:

Container No.	Tare wt.	Gr. Wt.	Net wt.	Container No.	Tare wt.	Gr. Wt.	Net wt.
1/				**11/**			
2/				**12/**			
3/				**13/**			
4/				**14/**			
5/				**15/**			
6/				**16/**			
7/				**17/**			
8/				**18/**			
9/				**19/**			
10/				**20/**			
Total net weight of granules:							
Checked By(sign & Date):							

8.2 VISUAL INSPECTION OF TABLET:

Date: _____

Time Duration		**Quantity rejected**	**Done by**
From	**To**		

Total weight of rejected tablets: _____ Good Tablet weight: _____

% Yield: _____

Checked by (Production):
(Sign & Date)

Verified by (IPQA):
(Sign & Date)

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 22 of 22
Batch No:	**Batch Size (Kg):** 23.05 Kg/2.0 Lac.	**Supersedes No.:** Nil

8.3 YIELD RECONCILIATION:

•	Average weight of tablets (A)=: mg
•	Total weight of coated tablets (B) = Kg.
•	Quantity of coated tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
•	Samples (D)=
•	Yield= $\frac{C + D}{\text{Actual batch size}}$ 100 = **(NLT 98.00%)**

Checked By (Production):	**Verified By (IPQA):**

8.4 SAMPLING:

- After completion of the manufacturing activity batch card shall be checked by production executive and inform IPQA through analytical request after completion of compression process.

_____
Checked By (Production)

- IPQA shall review batch card and then visually inspect the bulk for physical appearance, labeling status, number of container etc. and will collect the sample as per SOP, and shall submit to QC for analysis.

_____
Checked By (IPQA)

8.5 FINAL REVIEW OF BATCH CARD ON SHOP FLOOR:

Production manager/Designee shall review the batch card will give his comment, if any.

_____
Checked By (Prod. Mgr.)

9.0 ANY DEVIATION:

Deviation No.	**Reason for deviation**

_____
Checked By (Prod. Manager)

10.0 HISTORY SHEET:

BMR No.	**New BMR No.**	**Revision No.**	**Reason of revision**	**Change control No.**
	--	00	--	--

	Prepared By	**Checked By**	**Approved By**
Signature			
Date			