

BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

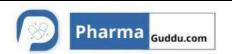
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Mfg. Date		Exp. Date						
Label Claim: Each uncoated tablet contains: Amlodipine Besilate BP equiv. to Amlodipine base 2.5 mg Colour: Erythrosine supra								
	ion: Store in cool, dry place.		Market: Domestic Shelf Life: 36 Months					
Reason for Re	vision: Change for Batch no. mat of BMR	Mfg. Location: (Tablet Area)						
Effective Date	:	Review Period: Recommendation on the basis of APR						
BMR Superse	des No. :	Product Code: I - AA						
MMF No.:		Standard Batch size: 1800,000 Tablets Weight of core tablet: 243.00 kg						
Reason for Iss	Reason for Issue: For Manufacturing							

Contents of Batch Manufacturing Record						
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5.	Process Deviation sheet	57				

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager DGM-Q		



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
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STAGE 1 (a): DISPENSING Date:

Equipment Name	Equipment Code No.	Operation SOP No.	Cleaning SOP No.
Reverse Laminar Air flow			
Dispensing Tools			
Area: Dispensing Area			

Check the following and take line clearance from QA as per SOP No. : QAD/XYZ Removal of previous product and batch □, Equipment cleanliness □, Area cleanliness □, Status Labelling □, Environmental condition □, Balance calibration record □, Equipment						
log shee	ts □, Pressure differential of LAF □.					
Previous	Product:	B. No. :				
	Checked by (Store)	Approved by (QA)				
Sign & Date						

INSTRUCTIONS:

- 1.1 Follow gowning procedure for respective area.
- 1.2 Use hand gloves, Safety goggles (wherever required) and nose mask during dispensing.
- 1.3 Operate the RLAFas per the SOP and Balances as per respective SOP
- 1.4 Dispense approved materials.

	Balances used							
Store	es/Date	Pro	oduction/Date					
Balance ID No.	Checked by	Balance ID No.	Checked by					
			-					

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager DGM-QA		



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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RAW MATERIAL ISSUANCE SHEET (Stores copy) BATCH SIZE- 1800,000 Tablets

Gra	nulation				I	Ory mixing	g (Lot- I))				
Sr. No	Item Code	Ingredients	U 0	Std. Quantity	Actual Quantity	Gross wt	Tare wt.	Net wt.	A.R. NO.	Issued by	Checked by	*Verified by Sign &
			М									Date
1.	RA-0005	Amlodipine Besilate BP	Kg	2.082								NA
2.	RL-0001	Lactose Monohydrate IP	Kg	19.50								NA
3.	RD-0002	Dicalcium Phosphate dihydrate IP	Kg	17.538								NA
4.	RS-0004	Starch IP**	Kg	34.344								NA
	•	•	,		Bind	ling (Lot -	-l)	•		•	•	•
1.	RS-0004	Starch IP**	Kg	1.524								NA
2.	RG-0001	Gelatin IP	Kg	0.540								NA
3.	RE-0003	Colour erythrosine supra IHS	Kg	0.058								NA
4.	RW-0001	#Purified water IP	Kg	16.500								NA

NOTE: The current monograph shall be used.

NA - Not Applicable

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer Executive QA		Plant Manager	DGM-QA	

^{*} Verify gross weight of all the raw material before start of processing (by production officer)

[#] Does not appear in final product and shall be dispensed by the production personnel

^{** 6%} starch extra to compensate LOD



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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RAW MATERIAL ISSUANCE SHEET(Stores copy) BATCH SIZE- 1800,000 Tablets Date:

Gra	nulation				I	Ory mixing	g (Lot- II)				
Sr. No	Item Code	Ingredients	U O M	Std. Quantity	Actual Quantity	Gross wt	Tare wt.	Net wt.	A.R. NO.	Issued by	Checked by	*Verified by Sign & Date
1.	RA-0005	Amlodipine Besilate BP	Kg	2.082								NA
2.	RL-0001	Lactose Monohydrate IP	Kg	19.50								NA
3.	RD-0002	Dicalcium Phosphate dihydrate IP	Kg	17.538								NA
4.	RS-0004	Starch IP**	Kg	34.344								NA
	l	•	1		Bind	ling (Lot	-II)		ı	·		1
1.	RS-0004	Starch IP**	Kg	1.524								NA
2.	RG-0001	Gelatin IP	Kg	0.540								NA
3.	RE-0003	Colour erythrosine supra IHS	Kg	0.058								NA
4.	RW-0001	#Purified water IP	Kg	16.500								NA

NOTE: The current monograph shall be used.

NA - Not Applicable

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer Executive QA		Plant Manager	DGM-QA	

^{*} Verify gross weight of all the raw material before start of processing(by production officer)

[#] Does not appear in final product and shall be dispensed by the production personnel

^{** 6%} starch extra to compensate LOD



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Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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RAW MATERIAL ISSUANCE SHEET(Stores copy) BATCH SIZE- 1800,000 Tablets Date:

Gra	nulation				I	Dry mixing	g (Lot- II	I)				
Sr. No	Item Code	Ingredients	U O M	Std. Quantity	Actual Quantity	Gross wt	Tare wt.	Net wt.	A.R. NO.	Issued by	Checked by	*Verified by Sign & Date
1.	RA-0005	Amlodipine Besilate BP	Kg	2.082								NA
2.	RL-0001	Lactose Monohydrate IP	Kg	19.50								NA
3.	RD-0002	Dicalcium Phosphate dihydrate IP	Kg	17.538								NA
4.	RS-0004	Starch IP**	Kg	34.344								NA
	•		1		Bind	ling (Lot -	-III)		•	l.	1	1
1.	RS-0004	Starch IP**	Kg	1.524								NA
2.	RG-0001	Gelatin IP	Kg	0.540								NA
3.	RE-0003	Colour erythrosine supra IHS	Kg	0.058								NA
4.	RW-0001	#Purified water IP	Kg	16.500								NA

NOTE: The current monograph shall be used.

NA - Not Applicable

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		

^{*} Verify gross weight of all the raw material before start of processing(by production officer)

[#] Does not appear in final product and shall be dispensed by the production personnel

^{** 6%} starch extra to compensate LOD



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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RAW MATERIAL ISSUANCE SHEET(Stores copy) BATCH SIZE- 1800,000 Tablets Date:

	Extra granular material											
	Item Code	Ingredients	U	Std.	Actual	Gross	Tare	Net	A.R. NO.	Issued	Checked	*Verified
			0	Quantity	Quantity	wt	wt.	wt.		by	by	by
			М									Sign & Date
1.	RD-0006	Dried Maize Starch BP	Kg	12.843								NA
2.	RS-0002	Sodium Starch Glycollate IP	Kg	4.266								NA
3.	RT-0002	Purified Talc IP	Kg	2.700								NA
4.	RA-0001	Colloidal Silicon Dioxide IP	Kg	0.900								NA
5.	RM-0002	Magnesium Stearate IP	Kg	1.620								NA

NOTE: The current monograph shall be used.

NA - Not Applicable

Raw Material Received By : (Production) Sign & Date

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		

^{*} Verify gross weight of all the raw material before start of processing (by production officer)



BATCH MANUFACTURING RECORD

Generic Name: Amlodipine Besilate Tablets Product: Amlovas 2.5

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STAGE 2: GRANULATION AREA LINE CLEARANCE

Date:

Equipment Name	Equipment Code No.	Operation SOP No.	Cleaning SOP No.
Vibro sifter			
Multi mill			
Rapid mixer granulator			
Paste kettle			
Fluid bed dryer			
Octagonal Blender			
Previous Product:-			Batch No.

Check the following and take line clearance from QA as per SOP Removal of previous product and batch □, Equipment cleanliness □, Area cleanliness □ Status Labelling □, Environmental condition □, Balance calibration record □, Equipmer log sheets □, Pressure differential of room □. Swab test passed □. Swab test analytica report no							
Sign & Date							
	Checked by (Production)	Approved by (QA)					

INSTRUCTIONS:

Follow these general precautions before starting the manufacturing

- 1. Ensure that secondary gowning of the respective area is followed.
- 2. Wear hand gloves, nose mask and safety goggles, ear muffs (if required) at all stages of manufacturing
- 3. Ensure all equipments are cleaned and having status label.
- 4. Ensure that temperature is 23 \pm 2°C and Relative Humidity is 50% \pm 5
- 5. Ensure that all SOP's are followed at all stage of manufacturing.
- 6. Preserve the equipment cleaning status label along with the BMR for product change over.7. Preserve all the Raw Material labels along with the BMR after completion of the granulation process.

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



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STAGE 3: MANUFACTURING PROCESS INSTRUCTIONS:

3.1 Raw Material Sifting

- 3.1.1 Ensure that all the Raw materials weights are crosschecked before processing.
- 3.1.2 Transfer Amlodipine Besylate (2.082 kg),Lactose mono hydrate (19.500 kg), Dicalcium phosphate (17.538 kg), Starch (34.344 Kg), Starch (1.524 Kg), from the day store to sifting area.
- 3.1.3 Ensure that the sieves are cleaned before use.
- 3.1.4 Check the sieve integrity before and after sifting.
- 3.1.5 Collect the sifted material into a cleaned container lined with double polythene bag.
- 3.1.6 Sifting of the raw material to be done lot wise. Keep the sifted material separately for its separate identity.
- 3.1.7 Sift the amlodipine Besilate, lactose monohydrate, Dicalcium phosphate dihydrate IP, and starch as per below mentioned sieve size.
- 3.1.8 Follow same procedure from step no. 3.1.2 to 3.1.7 for Lot II and Lot III and record details in respective table

Table	e No. 3.1.1	ial Sifting (Lot – I)							
Siftin	Sifting started at:			Complet	Completed at:					
Sr.	Material	Qty.	Sieve	Sieve		Sieve Int	egrity		Done	Ckd by
No.		(kg)	Size	Code No.	Before	Ckd. by	After	Ckd. by	Ву	
1.	Amlodipine Besilate BP	2.082	40#							
2.	Lactose Monohydrate IP	19.50	40#							
3.	Dicalcium Phosphate dihydrate IP	17.538	40#							
4.	Starch IP	34.344	60#							
5.	Starch IP	1.524	60#							

Table	Table No. 3.1.2 Raw M			aterial Siftir	ıg (Lot – II)				
Sifti	Sifting started at :			Completed at:					Date:	
Sr.	Material	Qty.	Sieve	Sieve		Sieve Int	egrity		Done	Ckd by
No.		(kg)	Size	Code No.	Before	Ckd. by	After	Ckd. by	Ву	
1	Amlodipine Besilate BP	2.082	40#							
2.	Lactose Monohydrate IP	19.50	40#							
3.	Dicalcium Phosphate dihydrate IP	17.538	40#							

Prepared By	Checked	Ву	Approved By			
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Prod	duct: Amlovas 2.5	Ge	Generic Name: Amlodipine Besilate Tablets									
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4.	Starch IP	34.344	60#									
5.	Starch IP	1.524	60#									

Sifting started at :			Completed at:				Date:			
Sr.	Material	Qty.	Sieve	Sieve		Sieve Int	egrity		Done Ckd by	
No.		(kg)	Size	Code No.	Before	Ckd. by	After	Ckd. by	Ву	
1.	Amlodipine Besilate BP	2.082	40#							
2.	Lactose Monohydrate IP	19.50	40#							
3.	Dicalcium Phosphate dihydrate IP	17.538	40#							
4.	Starch IP	34.344	60#							
5.	Starch IP	1.524	60#							

3.2 : BINDER SOLUTION PREPARATION RECORD

INSTRUCTIONS:

Table No. 3.1.2

3.2.1 Prepare the binder solution as per following procedure for three lots.

Raw Material Sifting (Lot - III)

3.2.2 Record details in respective tables.

Tab	Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-I)					
Sr.	Operation	Tim	ne	Done by	Checked by	Date
No.		From	То			
1	Take the purified water (5.0 lt.)in paste preparation vessel and heat it. and add the gelatin 0.540 kg in while stirring					
2	Take the Purified water(6.5 lt.) in cleaned SS container and add the Colour erythrosine supra (0.058 kg) in it while stirring					
3	Take the Purified water(5.0 lt.) in cleaned SS container and add the starch (1.524 kg)in it while stirring					
4	Add the solution of step No. 2&3 in step No. 1 under stirring and heat till the clear lump free suspension obtained.					
5	Cool the solution upto the 45°C					

TEST	STANDARD	OBSERVATION	CHECKED BY	DATE

Prepared By	Checked By		Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	Amlodipine Besilate Tablets		
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Appearance of solution	Clear paste		

Tab	Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-II)					
		From	То			
1	Take the purified water (5.0 lt.)in paste preparation vessel and heat it. and add the gelatin 0.540 kg in while stirring					
2	Take the Purified water(6.5 lt.) in cleaned SS container and add the Colour erythrosine supra (0.058 kg)in it while stirring					
3	Take the Purified water(5.0 lt.) in cleaned SS container and add the starch (1.524 kg) in it while stirring					
4	Add the solution of step No. 2&3 in step No. 1under stirring and heat till the clear lump free suspension obtained.					
5	Cool the solution up to the 45°C			_		

TEST	STANDARD	OBSERVATION	CHECKED BY	DATE
Appearance of solution	Clear paste			

Tab	Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-III)					
		From	То			
1	Take the purified water (5.0 lt.) in paste preparation vessel and heat it. and add the gelatin 0.540 kg in while stirring					
2	Take the Purified water(6.5 lt.) in cleaned SS container and add the Colour erythrosine supra (0.058 kg)in it while stirring					
3	Take the Purified water(5.0 lt.) in cleaned SS container and add the starch (1.524 kg)in it while stirring					
4	Add the solution of step No. 2&3 in step No. 1 under stirring and heat till the clear lump free suspension obtained.					
5	Cool the solution up to the 45°C					

TEST	STANDARD	OBSERVATION	CHECKED BY	DATE
Appearance of solution	Clear paste			

Prepared By	Checked By		Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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Prepared By	Checked By		Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



Date:

BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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STAGE 3.3: DRY MIXING & GRANULATION

DRY MIXING: INSTRUCTIONS

- 3.3.1 Mix the sifted Amlodipine Besilate BP, Lactose Monohydrate IP, Dicalcium, Phosphate dihydrate IP, Starch IP in geometric proportion.
- 3.3.2 Load Amlodipine Besilate BP (2.082 Kg), Lactose Monohydrate IP (19.50 Kg) Dicalcium Phosphate dihydrate IP (17.538 kg), Starch IP (34.344 kg) into rapid mixer granulator.
- 3.3.3 Operate the RMG as per their SOP.
- 3.3.4 Dry mix for 7 minutes at slow agitator speed.
- 3.3.5 Add the binder solution after dry mixing at slow speed
- 3.3.6 Granulate the material at agitator and chopper at slow speed for 20 to 25 minutes.
- 3.3.7 Run the agitator at fast speed and chopper at slow speed for 2 minutes.
- 3.3.8 Check the integrity of FBD bowl mesh. Unload the Wet mass into two FBD bowls in approximately equal quantity during unloading agitator/chopper will run at slow speed.
- 3.3.9 Granulation of the material to be done in three lots.
- 3.3.10 Follow same procedure for remaining lot and record details in Table No. 3.3.1

DRY MIXING & GRANULATION DETAILS

	Table No.:3.3.1								
	3.3.1.1 Material Loading Details								
Sr. No.	Particulars	Date	Date	Date					
		LOT – I (Qty. in Kg)	LOT – II (Qty. in Kg)	LOT – III (Qty. in Kg)					
1.	Amlodipine Besilate BP	2.082	2.082	2.082					
2.	Lactose Monohydrate IP	19.50	19.50	19.50					
3.	Dicalcium Phosphate dihydrate IP	17.538							
4.	Starch IP	34.344 34.344		34.344					
	Done By :								
	Date								
	Started At:								
ial ng	Completed At								
<u>Material</u> Loading	Done By :								
M _i	Checked By:								

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
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3.3.1.2 Dry Mixing Details								
		Date						
			Lot	- I	Lot	- 11	Lot	- III
		(7 min.)						
bu		Started At:						
Ξ X X		Completed At:						
Dry Mixing		Done By						
		Checked By						
		Date						
		3.3.1.3 Binder solution	adding De	etails(Gran	ulation Re	cord)	1	
		Date						
an tio	Started At: Completed At:							
Gran ulatio								
		Agitator						
ge ding		Chopper						
Amperage Reading	(Section 2)	Done By						
A A		Checked By						
Amount	of e	extra purified water added Kg						
		3.3.1.4 Unload	ling Detail	s into FBD	Bowl			,
			Lo	ot I	Lo	t II	Lot III	
Date			Bowl 1	Bowl 2	Bowl 1	Bowl 2	Bowl 1	Bowl 2
		Sieve integrity of Bowl						
d by	Started At:							
Checked by	Completed At:							
ပ်		Done By						
	Checked By							

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer Executive		Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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Prepared By	Checked	l By	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

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STAGE 3.4: DRYING

INSTRUCTIONS:

- 3.4.1 Place the FBD bowl containing wet granules under the retarding chamber and fit it to the retarding chamber by operating the jack handle at the bottom.
- 3.4.2 Air dry the material for 5 minutes and then rake the material.
- 3.4.3 Start the blower and set inlet temperature of 60°C to 70°C.
- 3.4.4 Dry the material till outlet reaches 41 to 43°C.
- 3.4.5 Shake the finger bag after switching off FBD. Hammer the retarding chamber gently and ensure that fine particles to settle before taking out the bowl.
- 3.4.6 Take samples of dried granules from FBD Bowl. Check the LOD of dried granules (Limit NMT3% w/w at 105°C)
- 3.4.7 Record details in respective table

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



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Product: Amlovas 2.5 Ge	Seneric Name:	Amlodipine Besilate Tablets
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Table No.3.4.1				Drying (Lot-I)				
				Bowl : 1				Da	ate:
Stage Time		me (in min.)		Time	Te	emper	ature (°C)	Done By	Checked By
			From	n To	In	let	Outlet		
Air Drying		5							
Raking									
Steam Drying									
Raking									
Steam Drying									
LOD of granules :				Limit :	NMT 3% w/	w at 1	05°C		
sieve integrity of	bow	l after drying	OK/N	от ок			Checked by		
FBD bag No					(FBD bag	g inte	grity)		
		Before dr	ying	Ckd	by		After drying		Ckd by
	-								
				Bowl : 2				 Da	ate :
Stage	Ti	ime (in min.)			т	Temperature (°C)		Done By	Checked By
- Lange		,	From			Inlet Outlet		200 2,	
Air Drying		5	11011	. 10		iici	Outlet		
Raking		<u> </u>							
Steam Drying									
Raking									
Steam Drying									
LOD of granules :			<u> </u>	Limit :	I NMT3% w/\	w 105	°C		
Sieve integrity of	bow	l after drving	OK/NO	OT OK			Checked by		
FBD bag No			(FBD bag integrity)						
					,. == εαξ		<i>וניי</i> יט		
	Before dr			Ckd	by	After drying		g Ckd by	
	-					1			

Prepared By	Checked	Ву	Approved By		
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Table No.3.4.2			D	rying	(Lot-II)					
			Bowl : 1				Date :	Date :		
Stage	Time	(in min.)	Tir	ne	Te	emperatu	re (°C)	Done B	By Checked By	
			From	m To		let	Outlet			
Air Drying		5								
Raking										
Steam Drying										
Raking										
Steam Drying										
LOD of granules :				Limit :	3% w/w 10	5°C				
Sieve integrity of	f bowl a	fter drying	OK/NOT	OK		С	hecked b	y		
FBD bag No			(FBD bag i	ntegrity	/)					
						_				
			Before dr	ying	Ckd	by	After	drying	Ckd by	
			Bow	/l : 2	Date :					
Stage	Time	(in min.)	Time		Te	Temperature (°C)		Done B	By Checked By	
			From	To) In	let	Outlet			
Air Drying		5								
Raking										
Steam Drying										
Raking										
Steam Drying										
LOD of granules	Limit :NMT 3% w/w 105°C									
Sieve integrity of	bowl at	fter drying	OK/NOT C	K		CI	necked by	•		
EDD D C - !					(FBD I	(FBD Bag Integrity)				
FBD Bag Code	no.	Before	Drying	Ck	kd by	At	After Drying		Ckd by	
					· ·		, ,		·	

Prepared By	Checked By		Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



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Table No.3.4.3				Dı	rying (Lot	-III)					
				Bow	l : 1					Da	te :
Stage	Time	(in min.)		Tin	пе	Te	mper	ature (°C)	Do	ne By	Checked By
			Fron	n	То	Inl	et	Outlet			
Air Drying		5									
Raking											
Steam Drying											
Raking											
Steam Drying											
LOD of granules :					Limit : NMT	3% w/v	v 105	°C			
Sieve integrity of	bowl a	fter drying	OK/N	от о	K			Checked by			
FBD Bag Code no.					(FBD Bag In	tegrity)					
		Before Dry	/ing		Ckd by			After Drying			Ckd by
				Bow	l : 2		I			Da	te :
Stage	Time	(in min.)		Tin	пе	Те	mper	ature (°C)	Do	ne By	Checked By
			Fron	n	То	Inl	et	Outlet			
Air Drying		5									
Raking											
team Drying											
Raking											
Steam Drying											
LOD of granules :					Limit : NMT	3% w/w	/ 105°	°C0			
Sieve integrity of	bowl a	fter drying	OK/N	от о	K			Checked by			
EDD D 0 - 1						(FBD B	ag In	tegrity)			
FBD Bag Code	no.										
		Before	Drying		Ckd by			After Drying			Ckd by

Prepared By	Checked By		Approved By	
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BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No. :	B. No.:	Page 19 of 57

STAGE 3.5 : Sifting and Milling

Date:

INSTRUCTIONS:

- 3.5.1 Sift the dried granules through 20 # sieve using sifter and pass retention over the sifter sieve by using multi mill using 2.0 mm screen at medium speed and knives forward direction. Collect the milled granules in IPC.
- 3.5.2 Sift milled material through 20 # sieve using sifter and continue till all the granules are passed through 20 # sieve. Collect the granules in IPC and label them properly.

3.5.3 Record details in table no. 3.5.1

			Tab	le No.	3.5.1				
Date / Lot No & Bowl no	Activity	Screen /sieve size & No.	Screen/Sieve integrity (before use)	Ckd by	Started at	Compl eted at	Screen /Sieve integrity (after use)	Done by	Checke d by
	Sifting	(#20)							
Lot-I (Bowl-1)	Milling	(2.0mm)							
	Sifting	(#20)							
	Sifting	(#20)							
Lot-I (Bowl-2)	Milling	(2.0mm)							
	Sifting	(#20)							
	Sifting	(#20)							
Lot II (Bowl-1)	Milling	(2.0mm)							
	Sifting	(#20)							
	Sifting	(#20)							
Lot II (Bowl-2)	Milling	(2.0mm)							
	Sifting	(#20)							
	Sifting	(#20)							
Lot III (Bowl-1)	Milling	(2.0mm)							
	Sifting	(#20)							
	Sifting	(#20)							
Lot III (Bowl-2)	Milling	(2.0mm)							
	Sifting	(#20)							

Ensure that all granules should pass through 20#

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BATCH MANUFACTURING RECORD

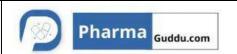
	Generic Name: Amlodipine Besilate	
BMR No.:	B. No.:	Page 20 of 57

Table No.3.5.2 Sifted & Milled Granules Weighing						
Balance	ID no. :	Date:				
Sr. No.	container No.	Gross wt. (kg)	Tare wt. (kg)	Net wt. (kg)	Done by	Checked by
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9						
10						
11						
12						
Theoretic	al weight-22	0.67kg	Γotal net wt. →	1	•	•

	Actual weight			
% Yield =	x 100	=	%	(Limit : NLT 99.5 %)
	Theoretical weight			

Checked by Sign & Date: Sign & Date: (production) Verified by Sign & Date: (QA)

Prepared By	Checked By		Approved By	
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BATCH MANUFACTURING RECORD

BMR No. :	B. No.:	Page 21 of 57
Product: Amlovas 2.5	Generic Name: Amlodipine Besilat	e Tablets

STAGE 3.6: BLENDING

INSTRUCTIONS:

Extra Granular Material Sifting

- 3.6.1 Ensure that all the Raw materials weights are crosschecked before processing.
- 3.6.2 Transfer Starch (Dried) (12.843 kg), Sodium Starch Glycollate (4.266kg), Purified Talc (2.70 kg), Colloidal Silicon Dioxide (0.900kg), Magnesium Stearate (1.620 Kg) to sifting area
- 3.6.3 Ensure that the sieves are cleaned before use.
- 3.6.4 Check the sieve integrity before and after sifting.
- 3.6.5 Collect the sifted material into a cleaned pre-labelled In Process Containers...
- 3.6.6 After sifting magnesium stearate shall be kept separately and record details in table no. 3.6.1

Table	Table No. 3.6.1 Extra Granular Material Sifting								
Sifting started at :		Completed at :				Date:			
Sr. No.	Material Qty. Sieve Sieve Integrity Starte at			Comp leted	Done By	Check ed by			
		(1.9)	Code	Before	After		at		
			No.	Checked by					
1.	Dried Starch BP	12.843							
2.	Sodium Starch Glycollate IP	4.266	60 #						
3.	Purified Talc IP	2.700							
4.	Colloidal Silicon Dioxide IP	0.900							
5.	Magnesium Stearate IP	1.620							

- 3.6.7 Load the sifted and milled granules into Octagonal blender and then load sifted lubricants (except Magnesium Stearate) and mix for 25 minutes at slow speed.
- 3.6.8 Load sifted Magnesium stearate to the Octagonal blender and mix for 3 minutes at slow speed.
- 3.6.9 Unload the blended granules into clean double polythene lined SS container and label properly. Weigh and record the weight of each container in weighing record of lubricated granules.

Prepared By	Checked By		Approved By	
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BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets	

Table No. 3	3.6.2	Material loading Record				
From	Date:	Time:	То	Date:		Time:
Date:		Quantity	From	То	Done by	Checked
						by
Lot-I milled	granules					
Lot-II milled	granules					
Lot-III milled	d granules					
Dried Maize	Starch BP	12.843 Kg				
Sodium Sta	rch Glycollate IP	4.266 Kg				
Purified Tal	c IP	2.700 Kg				
Colloidal Si	licon Dioxide IP	0.900 Kg				
	Blending					
Blending f	rom to	(m	ninutes)		Date :	
Item		Quantity	Loaded by	From	То	Checked by
Magnesium	Stearate I.P.	1.620 kg				
Final blend	ling from	to (minutes)		Dat	e :

Lubricated granules unloading record from blender						
Date	From	То	Done by	Checked by		

Prepared By	Checked By		Approved By	
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BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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Table No	Table No. 3.6.3 Weighing of Lubricated Granules					
Balance					Date :	
Sr. No.	Gross wt. (kg)	Tare wt. (kg)	Net wt. (kg)	Done by	Checked by	
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
	Theoretical weight-	243.00Kg	Total wt. →			

(Limit: NLT 99.5%)

Checked By (QA) Sign & Date

Prepared By	Checked By		Appro	ved By
Officer QA	Production Officer Executive QA		Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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STAGE 3.7: COMPRESSION

Equipment Name	Equipment No.	Operation SOP No.	Cleaning SOP No.
Compression Machine	EQ/TAB/XYZ	TAB/XYZ	TAB/XYZ
Previous Product :	1	Batc	h No.

	TABLET COMPRESSION					
Removal of pre Labelling □, Er	•	t cleanliness □, Area cleanliness □, Status bration record □, Equipment log sheets □,				
Sign & Date						
	Checked by (Production)	Approved by (QA)				

	COMPRESSION PARAMETERS					
1	СОМ	PRESSION MACHINE	(29 STATION)			
	UPPER PU	_				
2		7.0 mmCircular Standard ConcaveA / 2.5				
	LOWER PUNCH					
3		: 7.0 mm : Circular Standard Concave : Plain				
4	RPM	: $27 \pm 3 \text{ RPM}$				
5		 Compression should be done at relative humidity of 50 ± 5% and temperature 23± 2 °C. Hopper should always be kept closed 				

Prepared By	Checked By		Approved By	
Officer QA	Production Officer Executive QA		Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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Table No. 3.7	7.1	INPROCESS SPECIFICATION				
S. No.	Parameter	Specification	Frequ	iency	No of tablets	
3. NO.	o. Farameter Specification		Production	QA	Req./side	
1	Appearance	Pink coloured circular shallow biconvex uncoated tablets embossed A score & 2.5 on one side and plain of other side of tablet	Every 1 hour	Every 1hrs.	40	
2	Weight of 40 tablets	5.40 g ± 2.0 % (5.292 to 5.508 g)	Every 30 min.	Every 1hrs.	40	
3	Thickness	2.9 <u>+</u> 0.2 mm	Every 2 hour	Every 2 hrs.	3	
4	Hardness	2.0 - 5.0 Kg/ cm ²	Every 2hour	Every 2 hrs.	3	
5	Disintegration time	NMT 15 minutes	Every 2 hour	Every 2 hrs.	6	
6	Friability	NMT 1.0%	Every 2 hour	Every 2 hrs.	20	
7	Uniformity of Weight	135 mg <u>+</u> 5.0 %	Every 2 hour	Every 2 hrs.	40	

Manufacturing instructions

- 1. Operate the tablet compression machine as per SOP.
- 2. Check for punch specification before starting the operation and note down the details in **Start-up test during tablet** compression Punch inspection details
- 3. Transfer the SS containers with blend from quarantine area to the compression area. Check the no. of containers and the quantity of blend received from quarantine area for compression
- 4. Set the compression machine for the specified parameters as per above specification and note down the details in **Start-up** test during tablet compression (Verification of tablet parameters)
- 5. Load the granules by the container No. wise
- 6. Destroy the tablets during the first few rounds of compression as per SOP.
- 7. Connect the tablet-dedusting machine to the compression machine in such a way that all compressed tablets are passed through the dedusting machine before being collected in storage drums.
- 8. Carry out the Inprocess checks as per the frequency given above and note down the details in the respective tables.
- 9. Do the start-up test after every stoppage of machine for one shift / any major breakdown.
- 10. Caution:
- Compressed tablets are to be unloaded into SS containers lined with double poly bags. Tie inner poly bag and then second poly bag is to be tied. Keep closed and weighed containers under quarantine (Tablet quarantine area) with proper label.
- 11. Send the test requisition form to QA for collecting of sample.

During in-process checks 40 Tablets shall be withdrawn and	d to be collected in primary co	ntainer. QA shall withdraw 50 Tablets
from primary container label it and send to QC with analysis	request note.	
No of containers received from blending stage	_ and quantitykgs	Checked by:
Quantity of Tablets destroyed during the first few round	s Nos.	Checked by:

Prepared By Checked By			Approv	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name:	Amlodipine Besilate Tablets
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Table No.3	3.7.2	Machine Start and End Details						
Started at		Done by Checked by		Completed at		Done by	Checked by	
Date	Time			Date	Time			
Compress the	whole Batch wi	th the above specif	i fication .The abov	e parameters have t	o be checked by c	oncerned production	supervisor and QA	
officer								

Start-up test during tablet compression Punch inspection details

			, an	on map	cciion a	ctans				
Note: Enter "√" if p complying w						d no damag	e is seen E	Enter "X" if p	ounch is not	
Upper Punch No	1	2	3	4	5	6	7	8	9	10
Description										
Upper Punch No	11	12	13	14	15	16	17	18	19	20
Description										
Upper Punch No	21	22	23	24	25	26	27	28	29	
Description										
					•	•				
Lower Punch No	1	2	3	4	5	6	7	8	9	10
Description										
Lower Punch No	11	12	13	14	15	16	17	18	19	20
Description										
Lower Punch No	21	22	23	24	25	26	27	28	29	
Description										
Punch inspection de Sign & Date	one by Pr	oduction:			Punch ir Sign & D	nspection o Date	checked by	QA:		

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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Prepared By	Checked	l By	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No. :	B. No.:	Page 28 of 57

	Table No. 3.7.3 1 st Start-up test during tablet compression (Verification of tablet parameters)								
Sr. No	Test		LHS	S		RHS			
1.	Weight of 40 tablets 5.40 g ± 2 % (Limit 5.292 to 5.508) g		g			g			
2.	Appearance of 40 tablets								
3.	Weight variation of 40 tablets 135.0 mg ± 5.0 % Limit: 128.2 to 141.7 mg								
4.	<i>Thickness of 40 tablets</i> 2.9 ± 0.2 mm (Limits 2.70 – 3.10 mm)								
5.	Hardness 2.0-5.0 Kg/cm ²								
6.	DT (NMT 15mins)								
7.	Friability (NMT 1%)								
	Parameters checked by Production: § Date		Table Sign	t Parame & Date	ters checke	ed by QA:			

Note: Theoretical average weight is 135.0 mg

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No. :	B. No.:	Page 29 of 57

Sr.	No. 3.7.3 2 nd Start-up test o			, : :::::::::::::::::::::::::::::::::::			
No	Test		LHS			RHS	
1.	Weight of 40 tablets 5.40 g ± 2 % (Limit 5.292 to 5.508) g		g			g	
2.	Appearance of 40 tablets						
3.	Weight variation of 40 tablets 135.0 mg ± 5.0 % Limit: 128.2 to 141.7 mg						
4.	Thickness of 40 tablets $2.9 \pm 0.2 \text{ mm}$ (Limits $2.70 - 3.10 \text{ mm}$)						
5.	Hardness 2.0-5.0 Kg/cm ²		•				
6.	DT (NMT 15 mins)	'	<u> </u>	,	·	<u>'</u>	ı
7.	Friability (NMT 1%)						
	Parameters checked by Production: & Date		Tablet Para Sign & Date	meters checke	d by QA:		

Note: Theoretical average weight is 135.0 mg

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No. :	B. No.:	Page 30 of 57

Sr. No	Test		LH	S			RHS	
1.	Weight of 40 tablets 5.40 g ± 2 % (Limit 5.292 to 5.508) g		g		_	g		
2.	Appearance of 40 tablets							
<i>3</i> .	Weight variation of 40 tablets 135.0 mg ± 5.0 % Limit: 128.2 to 141.7 mg							
4 .	Thickness of 40 tablets 2.9 ± 0.2 mm (Limits 2.70 – 3.10 mm)							
5.	Hardness 2.0-5.0 Kg/cm ²							
6.	DT (NMT 15 mins)	•	•	•		•		•
7.	Friability (NMT 1%)							

Note: Theoretical average weight is 135.0 mg

Prepared By	Checked	I By	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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Table no. 3.7.4 Compression In-process Record (LHS) Frequency Every 30 minutes (Production)									cord	(LHS)	Freq	uenc	y Eve	ery 30) min	utes	(Pro	on)		
Weight											,							•	ate :		
Time								,,				9									
5.535																					
5.520																					
5.505																					
5.490																					
5.475																					
5.460																					
5.445																					
5.430																					
5.415																					
5.400																					
5.385																					
5.370																					
5.355																					
5.340																					
5.325																					
5.310																					
5.295																					
5.280																					
5.265																					
Sign																					
C	ompre	essio	n In-	proc	cess	Reco	rd (R	HS)		Fre	quer	cy E	very	30 m	inute	s (Pr	oduc	tion))		
Time																					
5.535																					
5.520																					
5.505																					
5.490																					
5.490 5.475																					
5.475 5.460																					
5.475 5.460 5.445																					
5.475 5.460 5.445 5.430																					
5.475 5.460 5.445																					
5.475 5.460 5.445 5.430 5.415																					
5.475 5.460 5.445 5.430 5.415 5.400																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310																					
5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295 5.280																					

X - Axis : Time Y - Axis : Weight of 40 Tablets (Each unit is equivalent to 0.015 g)

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

BMR No.: Page 32 of 57

Frequency Every 30 minutes (Production) Table No. 3.7.4Compression In-process Record (LHS) Weight of 40 Tablets: Minimum: 5.292 g, Maximum: 5.508 g Date: 5.535 5.520 5.505 5.490 5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295 5.280 5.265 Sign Frequency Every 30 minutes (Production) Compression In-process Record (RHS) Time 5.535 5.520 5.505 5.490 5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295 5.280 5.265

X - Axis : Time Y - Axis : Weight of 40 Tablets (Each unit is equivalent to 0.015 g)

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

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Table No. 3.7.4 Compression In-process Record (LHS) Frequency Every 30 minutes (Production) Weight of 40 Tablets: Minimum: 5.292 g, Maximum: 5.508 g Date: 5.535 5.520 5.505 5.490 5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295 5.280 5.265 Sign **Compression In-process Record (RHS)** Frequency Every 30 minutes (Production) Time 5.535 5.520 5.505 5.490 5.475 5.460 5.445 5.430 5.415 5.400 5.385 5.370 5.355 5.340 5.325 5.310 5.295 5.280 5.265

X - Axis : Time Y - Axis : Weight of 40 Tablets (Each unit is equivalent to 0.015 g)

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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Table No. 3.7	'.5		INF	INPROCESS CHECKS				Frequency: Every 2 hours (Production)				
Date	Time	%Fria (Limit N	ability IMT 1%)	Thickness (Limit 2.70	s (in mm.) 0-3.10 mm)	Hard 2.0-5.0	ness Kg/cm²	D (NMT [^]	.T. I5 Min.)	Done By	Ckd. By	
		L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	,		
]				
								1				
								1				
								1				
								1				
								1				
	1	1	1	1	1		1	1	1	1		

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name:	Amlodipin	e Besilate	Tablets
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Table No. 3.7.5	5	INPROCESS CHECKS Frequency: Every 2 hours (Production)									
Date	Time	%Friability (Limit NMT 1%)		Thickness (in mm.) (Limit 2.70-3.10 mm)		Hardness 2.0-5.0 Kg/cm ²		D.T. (NMT 15 Min.)		Done By	Ckd. By
		L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	_,	
								1			
								}			
								-			
								-			
								-			
											1

Prepared By	Checked	Ву	Approved By		
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA	



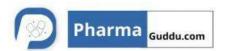
BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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Table No. 3.7.6 INPROCESS CHECKS													
	Ammourous of the telelate												
Date Time		Appear	Appearance of the tablets								%	Checked	
	Capping		Chipping		Sticking		Broken tablets		Discoloration			Ву	
		LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		

Prepared By	Checked	Ву	Approved By			
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA		



BATCH MANUFACTURING RECORD

 Product : Amlovas 2.5
 Generic Name: Amlodipine Besilate Tablets

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Put "X" for nil Rejection

Prepared By	Checked	Ву	Approv	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

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		7 Limit	= 135.0	mg ± 5.	0 % (Li		.2 mg t	1.7 mg)		ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date:								Date :							
Time :		is			RH	15		Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.		1.		21.		1.		21.	
2.		22.		2.		22.		2.		22.		2.		22.	
3.		23.		3.		23.		3.		23.		3.		23.	
4.		24.		4.		24.		4.		24.		4.		24.	
5.		25.		5.		25.		5.		25.		5.		25.	
6.		26.		6.		26.		6.		26.		6.		26.	
7.		27.		7.		27.		7.		27.		7.		27.	
8.		28.		8.		28.		8.		28.		8.		28.	
9.		29.		9.		29.		9.		29.		9.		29.	
10.		30.		10.		30.		10.		30.		10.		30.	
11.		31.		11.		31.		11.		31.		11.		31.	
12.		32.		12.		32.		12.		32.		12.		32.	
13.		33.		13.		33.		13.		33.		13.		33.	
14.		34.		14.		34.		14.		34.		14.		34.	
15.		35.		15.		35.		15.		35.		15.		35.	
16.		36.		16.		36.		16.		36.		16.		36.	
17.		37.		17.		37.		17.		37.		17.		37.	
18.		38.		18.		38.		18.		38.		18.		38.	
19.		39.		19.		39.		19.		39.		19.		39.	
20.		40.		20.		40.		20.		40.		20.		40.	
		We	eight of	40 table	ets					We	eight of	40 tabl	ets		
			g				g				g				g
			Average	Weigh	t					ı	Average	Weigh	ıt		
			mg				mg				mg				mg
			Maxi	mum							Maxii	num			
			mg				mg				mg				mg
			Mini	mum							Minir	num			
mg mg						mg				mg				mg	
Checked by						Checl	ked by								

Prepared By	Checked	Ву	Appro	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No.: Page 39 of 57

		7 Limit	= 135.0	mg ± 5.	.0 % (Li	mit 128	.2 mg t c	o 14			ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date :								Date : Time :								
Time :		10		I	D.	10			Time		10			-	10	
C	LF		\A/4 :	C.,	RH		\A/4 :		C.		HS	18/4 :	C		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.		8. 28. 8.						28.		
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
		ı	Average	Weigh	t						ı	Average	Weigh	t		
			mg				mg					mg				mg
			Maxi	mum								Maxir	num			
mg mg						mg					mg				mg	
			Mini	<u>l</u> mum								Minir	num			
mg mg					mg					mg				mg		
Checked by								Checl	ked by							

Prepared By	Checked	l By	Appro	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No.: Page 40 of 57

		7 Limit	= 135.0	mg ± 5.	.0 % (Li	mit 128	.2 mg t c	o 14			ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date :								Date : Time :								
Time :		10		I	D.	10			Time		10			-	10	
C	LF		\A/4 :	C.,	RH		\A/4 :		C.		HS	18/4 :	C		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.		8. 28. 8.						28.		
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
		ı	Average	Weigh	t						ı	Average	Weigh	t		
			mg				mg					mg				mg
			Maxi	mum								Maxir	num			
mg mg						mg					mg				mg	
			Mini	<u>l</u> mum								Minir	num			
mg mg					mg					mg				mg		
Checked by								Checl	ked by							

Prepared By	Checked	Ву	Appro	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No.: Page 41 of 57

		7 Limit	= 135.0	mg ± 5.	0 % (Li	mit 128	.2 mg t	o 141	1.7 mg)		ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date:								Date : Time :								
Time :		is			RH	15			Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in		Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg		No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		We	eight of	40 table	ets		ı				We	eight of	40 tabl	ets		
			g				g					g				g
		ı	Average	Weigh	t						ı	Average	Weigh	t		
			mg				mg					mg				mg
			Maxi	mum								Maxii	num			
			mg				mg					mg				mg
			Mini	num								Minir	num			
			mg				mg					mg				mg
Checked by								Check	ked by							

Prepared By	Checked	Ву	Appro	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No.: Page 42 of 57

		7 Limit	= 135.0	mg ± 5.	0 % (Li		.2 mg t	1.7 mg)		ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date:								Date :							
Time :		is			RH	IS.		Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.		1.		21.		1.		21.	
2.		22.		2.		22.		2.		22.		2.		22.	
3.		23.		3.		23.		3.		23.		3.		23.	
4.		24.		4.		24.		4.		24.		4.		24.	
5.		25.		5.		25.		5.		25.		5.		25.	
6.		26.		6.		26.		6.		26.		6.		26.	
7.		27.		7.		27.		7.		27.		7.		27.	
8.		28.		8.		28.		8.		28.		8.		28.	
9.		29.		9.		29.		9.		29.		9.		29.	
10.		30.		10.		30.		10.		30.		10.		30.	
11.		31.		11.		31.		11.		31.		11.		31.	
12.		32.		12.		32.		12.		32.		12.		32.	
13.		33.		13.		33.		13.		33.		13.		33.	
14.		34.		14.		34.		14.		34.		14.		34.	
15.		35.		15.		35.		15.		35.		15.		35.	
16.		36.		16.		36.		16.		36.		16.		36.	
17.		37.		17.		37.		17.		37.		17.		37.	
18.		38.		18.		38.		18.		38.		18.		38.	
19.		39.		19.		39.		19.		39.		19.		39.	
20.		40.		20.		40.		20.		40.		20.		40.	
		We	eight of	40 table	ets					We	eight of	40 tabl	ets		
			g				g				g				g
			Average	Weigh	t					ı	Average	Weigh	t		
			mg				mg				mg				mg
			Maxi	mum							Maxii	num			
			mg				mg				mg				mg
			Mini	mum							Minir	num			
mg mg						mg				mg				mg	
Checked by							Check	ked by							

Prepared By	Checked	l By	Appro	ved By
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 43 of 57

		7 Limit	= 135.0	mg ± 5.	.0 % (Li	mit 128	.2 mg t c	o 14			ncy : E	VERY 2	HOUR	S : PRO	DUCTI	ON
Date :								Date : Time :								
Time :		10		I	D.	10			Time		10			-	10	
C	LF		18/4 :	C.,	RH		\A/4 :		C-		HS	18/4 :	6-		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.		8. 28. 8.							28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
		ı	Average	Weigh	t							Average	Weigh	t		
			mg				mg					mg				mg
			Maxi	mum								Maxir	num			
			mg				mg					mg				mg
			Mini	l mum								Minin	num			
mg mg					mg					mg				mg		
Checked by								Checl	ked by							

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No. : Page 44 of 57

	No. 3.7.	/ Limit	= 135.0	mg ± 5.	.0 % (Li	mit 128	.2 mg t	o 141			ncy : E	VERY 2	HOUR	S : PRO	DUCII	ON
Date : Time :									Date :							
	LH	is			Rŀ	HS					HS			RI	HS	
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.	Ĭ	21.	Ĭ	1.		21.			1.		21.		1.		21.	Ĭ
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
		ı	Average	Weigh	t				Average Weight							
			mg				mg					mg				mg
			Maxi	mum								Maxii	num			
			mg				mg		mg					mg		
			Mini	mum								Minir	num			
			mg				mg					mg				mg
Check	ed by								Check	ked by						

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 45 of 57

Table No. 3.7.8 Compression In-process Record (LHS) Frequency Every 1 hour (QA)																			
Weight	of 40	Tak	lets	: Min	imun	า : 5.2	292 ლ	j, Ma	aximu	ım : 5	5.508	g					Da	ate :	
Time																			
5.535																			
5.520																			
5.505																			
5.490																			
5.475																			
5.460																			
5.445																			
5.430																			
5.415																			
5.400	-																		
5.385																			-
5.370																			
5.355																			
5.340																			
5.325																			
5.310																			
5.295																			
5.280																			
5.265																			
Sign																			
	ompr	oeei.	on In	nroc	220	Raco	rd (R	H6/		Fro	allen	cv F	VOTV	1 hou	ır (O	Λ)			=
Time	- I	COOL	011 111	proc	,033	\cco	14 (11	110)		1110	quei	Cy L	very	1 1100	וו (עני	<u> </u>			
5.535																			
5.520 5.505																			
5.490																			
5.490																			
5.460																			
5.445																			
5.445																			
5.430																			
5.415 5.400																			
5.385																			
5.370																			
5.355																			
5.340																			
5.325																			
5.310																			
5.295																			
5.280																			
5.265																			
Sign																			I

X - Axis : Time Y - Axis : Weight of 40 Tablets (Each unit is equivalent to 0.015 g)

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 46 of 57

Table No. 3.7.8 Compression In-process Record (LHS) Frequency Every 1 hour (QA)																				
Weight	of 40	Tab	lets	: Min	imun	า : 5.2	292 c	ı. Ma	aximu	ım : 5	5.508	a				,		Da	ate :	
Time								, ,												
5.535																				
5.520																				
5.505																				
5.490																				
5.475																				
5.460																				
5.445																				
5.430																				
5.415																				ļ
5.400																				
5.385																				
5.370																				
5.355																				ļ
5.340																				
5.325																				
5.310																				
5.295																				L
5.280																				
5.265																				
Sign																				
	ompre	essi	on In	-proc	ess	Reco	rd (R	HS)	•	Fre	quen	cy E	very	1 hou	ır (Q	A)				
Time																				
5.535																				
5.520																				
5.505																				
5.490																				
5.475																				
5.460																				
5.445	+																			<u> </u>
5.430	+																			-
5.415	+																			-
5.400																				
5.385	+																			-
5.370	+																			<u> </u>
5.355																				
5.340	+																			
5.325	+																			
5.310																				—
5.295	+																			
5.280																				-
5.265	+																			
Sign	+																			
V Avia									L							L	Ļ		<u> </u>	

X - Axis : Time Y - Axis : Weight of 40 Tablets (Each unit is equivalent to 0.015 g)

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

BMR No.: Page 47 of 57

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlova	s 2.5 Generic	Name: Amlodip	ine Besilate Tablets

BMR No.: Page 48 of 57

Table No.	3.7.9	_	INPROCESS CHECKS Frequency: Every 2 hours (QA)										
Date	Time	%Friability (Limit NMT 1%)		Thickness (in mm.) (Limit 2.70-3.10 mm) Hardness 2.0-5.0 Kg/cm²		2.0-5.0 Kg/cm ²		D.T. (NMT 15 Min.)		Done By			
		L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S				

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlova	s 2.5 Generic	Name: Amlodip	ine Besilate Tablets

BMR No.: Page 49 of 57

Γable No. 3	3.7.9	_	INPRO	quency: Every 2 hours (QA)						
Date	Time	%Fria (Limit NI	%Friability (Limit NMT 1%)		s (in mm.) 0-3.10 mm)		dness) Kg/cm²	D (NMT	.T. 15 Min.)	Done By
		L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	L.H.S	R.H.S	
	1	1								

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No.:	B. No.:	Page 50 of 57

Table N	No. 3.7.	10				IPROC							
		Appea	rance of t			equency:			%	Checked			
Date	Time	Сар	ping	Chip	ping	Stic	king		oken olets	Discoloration			Ву
		LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		
		1			1					1			
		1			1					1			
		1			1					1			
		 			 					 			
		1			1					1			
		 			 					 			

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

	DATOTI TATOTA OT ORITO RECORD													
Produc	t: Am	lovas 2	.5		Generi	ic Nam	e: Am	ets						
BMR No. :					B. No.:				Page 51 of 57					

Put "X" for nil Rejection

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 52 of 57

Table No. 3.7.11 Limit = $135.0 \text{ mg} \pm 5.0 \%$ (Limit 128)											equen	cy : EVE	RY 2 F	IOURS	: QA	
Date :									Date :							
Time :		10		ı		10			Time					-		
C		IS C-	18/4 im	C.,	RH		\A/4 :		C-		HS	18/4 :	6-		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t						ı	Average	Weigh	ıt		
			mg				mg					mg				mg
Maximum											Maxir	num				
mg m							mg					mg				mg
			Mini	<u>l</u> mum								Minir	num			
mg mg						mg					mg				mg	
Checked by						Checl	ked by									

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 53 of 57

Table No. 3.7.11 Limit = $135.0 \text{ mg} \pm 5.0 \%$ (Limit 128)								mg 1			equen	cy : EVE	RY 2 H	IOURS:	: QA	
Date :									Date :							
Time :		HS			RH	HS			Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in		Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg		No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t							Average	Weigh	t		
			mg				mg					mg				mg
			Maxi	mum								Maxir	num			
			mg				mg					mg				mg
			Mini	mum								Minin	num			
			mg				mg					mg				mg
Check	ed by								Check	ked by						

Prepared By	Checked	Ву	Approved By					
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA				



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No. : Page 54 of 57

Table No. 3.7.11 Limit = $135.0 \text{ mg} \pm 5.0 \%$ (Limit 128)											equen	cy : EVE	RY 2 F	IOURS	: QA	
Date :									Date :							
Time :		10		ı		10			Time					-		
C		IS C-	18/4 im	C.,	RH		\A/4 :		C-		HS	18/4 :	6-		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t						ı	Average	Weigh	ıt		
			mg				mg					mg				mg
Maximum							Maximum									
mg m						mg					mg				mg	
			Mini	<u>l</u> mum								Minin	num			
mg mg						mg					mg				mg	
Checked by							Checl	ked by								

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 55 of 57

	No. 3.7	'.11	Limit =	135.0 m	g ± 5.0 °	% (Lim	it 128.2	mg			equen	cy : EVE	RY 2 H	IOURS :	: QA	
Date :									Date :							
Time :		HS			RH	is.			Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in		Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg		No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t							Average	Weigh	it		
			mg				mg					mg				mg
Maximum											Maxii	num				
			mg				mg					mg				mg
			Mini	mum			Minimum									
			mg				mg					mg				mg
Checked by						Check	ked by		I							

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 56 of 57

	No. 3.7	.11	Limit =	135.0 m	g ± 5.0 °	% (Lim	it 128.2	mg			equen	cy : EVE	RY 2 H	IOURS	: QA	
Date :									Date :							
Time :		10				10			Time		10			-		
C		IS C-	18/4 im	C.	RH		\A/4 :		C-		HS	18/4 :	6-		HS	\A/4 :
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg		Sr. No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t						,	Average	Weigh	ıt		
			mg				mg					mg				mg
Maximum										Maxir	num					
			mg				mg	mg mg					mg			
			Mini	mum			Minimum									
			mg				mg					mg				mg
Checked by Cl					Checl	ked by										

Prepared By	Checked	l By	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 57 of 57

	No. 3.7	'.11	Limit =	135.0 m	ıg ± 5.0 '	% (Lim	it 128.2	mg 1			equen	cy : EVE	RY 2 H	IOURS	QA	
Date :									Date :							
Time :		10		ı		10			Time		10		1			
C		IS C.	18/4 im	C.,	RH		\A/4 :		C		HS	Wt in	RHS Sr. Wt in Sr. Wt ir			
Sr. No.	Wt in mg		Sr. No.	Wt in mg	Sr. No.	mg	No.	Wt in mg	No.	Wt in mg						
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t						1	Average	Weigh	it		
			mg				mg					mg				mg
			Maxi	mum								Maxir	num			
			mg				mg	mg mg						mg		
			Mini	l mum			Minimum									
			mg				mg					mg				mg
Check	red by			<u> </u>					Check	ked by						

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets

BMR No.: Page 58 of 57

	No. 3.7	'.11	Limit =	135.0 m	g ± 5.0 °	% (Lim	it 128.2	mg			equen	cy : EVE	RY 2 H	IOURS:	: QA	
Date :									Date :							
Time :		HS			RH	HS			Time		HS			RI	HS	
Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in		Sr.	Wt in	Sr.	Wt in	Sr.	Wt in	Sr.	Wt in
No.	mg	No.	mg	No.	mg	No.	mg		No.	mg	No.	mg	No.	mg	No.	mg
1.		21.		1.		21.			1.		21.		1.		21.	
2.		22.		2.		22.			2.		22.		2.		22.	
3.		23.		3.		23.			3.		23.		3.		23.	
4.		24.		4.		24.			4.		24.		4.		24.	
5.		25.		5.		25.			5.		25.		5.		25.	
6.		26.		6.		26.			6.		26.		6.		26.	
7.		27.		7.		27.			7.		27.		7.		27.	
8.		28.		8.		28.			8.		28.		8.		28.	
9.		29.		9.		29.			9.		29.		9.		29.	
10.		30.		10.		30.			10.		30.		10.		30.	
11.		31.		11.		31.			11.		31.		11.		31.	
12.		32.		12.		32.			12.		32.		12.		32.	
13.		33.		13.		33.			13.		33.		13.		33.	
14.		34.		14.		34.			14.		34.		14.		34.	
15.		35.		15.		35.			15.		35.		15.		35.	
16.		36.		16.		36.			16.		36.		16.		36.	
17.		37.		17.		37.			17.		37.		17.		37.	
18.		38.		18.		38.			18.		38.		18.		38.	
19.		39.		19.		39.			19.		39.		19.		39.	
20.		40.		20.		40.			20.		40.		20.		40.	
		W	eight of	40 table	ets						We	eight of	40 tabl	ets		
			g				g					g				g
			Average	Weigh	t						1	Average	Weigh	it		
			mg				mg					mg				mg
Maximum										Maxir	num					
			mg				mg	mg mg					mg			
			Mini	mum								Minin	num			
			mg				mg					mg				mg
Check	ed by								Check	ked by						

Prepared By	Checked	Ву	Approved By				
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA			



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5	Generic Name: Amlodipine Besilat	
BMR No.:	B. No.:	Page 59 of 57

Table No.	3.7.12	Weighing reco	ord of compressed tablets		
Balance Id	entification No.:				Date :
Sr. No.	Container No.	Gross wt. (kg)	Tare wt. (kg)	Net wt. (kg)	Done by
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
Th	eoretical weight (kg	g) =243.00	Total wt. →		

Theoretica	l Weight: 243.00Kg			
% Viold -	Actual weight	v 100 –	v 100 –	% (LIMIT : NLT 99.0 %)
76 Heid –	Theoretical weight		X 100 =	/6 (LIIVITI . INCT 99.0 /6)
Samples fo	or QC analysis	Nos.		
Non recov	erable rejects	Kg	Destroyed by	
			Checked by	(Production)
			Verified by	(QA)
Checked Sign & Da	by(Prod.): te :		-	pling done by (QA) & Date :

Prepared By	Checked By		Approved By	
Officer QA	Production Officer Executive QA		Plant Manager DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets	

4.0 TABLET INSPECTION

TABLET INSPECTION	Equipment No.	Operation SOP NO.	Cleaning SOP No.		
Tablet Inspection Belt	EQ/TAB/XX	TAB/XYZ	TAB/XYZ		
Metal Detector	EQ/TAB/XX	TAB/XYZ	IAD/ATZ		
Area: Inspection			PRD/XYZ		
Take Line clearance from QA a	s per SOP.				
Check the following					
	s□ Removal of Material of previous				
BMR/Records□ Temperature a	nd Relative humidity □ Equipment	log record □ Swab passed □ Swa	ab analysis report no		
Previous Product:		Batch No):		
Production		QA			
Sign, Date		Sign	, Date		
Quantity of tablet received: Kg Nos. Checked by:					

Transfer the tablets from the Tablet hold area to inspection area	
Transfer the tablets from the Tablet flow area to inspection area	

Visually inspect the tablets for physical defects. Segregate the rejected tablets (e.g. Tablets with foreign matter, oil stains. Capped tablets, broken tablets, chipped tablets etc) and collect them into separate labeled containers.

Operate the Metal detector as per their SOP No. (XYZ) and test the good tablets for metal traces by passing through metal detector. Weigh the rejected tablets and the good tablets for each container and enter the details in the below table. Label the containers and transfer them to the tablet hold area and reconcile the batch yield.

METAL DETECTOR CHALLENGE TEST FREQUENCY: EVERY START AND EVERY 4 HOURS

Metal Detector challenge test Non-Ferrous Non Magnetic Ferrous blocks blocks Steel(SS wire) embedded with Embedded with Checked by Done by **Embedded with** DATE/TIME (0.15 mm x 3mm) (0.2 mmx 3mm) (Prod.) (QA) (0.2mm x3mm) size of ferrous size of ss size of nonmaterial ferrous material material Kg_ Metal detector rejects quantity: _ Nos % (Investigation report to be attached, if any)

Date	Started at Completed at	Done by	Checked by (Prod Sign / date)
		1.	
		2.	
		1.	
		2.	

Prepared By	Checked By		Approved By	
Officer QA	Production Officer Executive QA		Plant Manager DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 Generic Name: Amlodipine Besilate Tablets	BMR No. :	B. No.:	Page 61 of 57
	Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets

alance ID No.				Date:			
Sr.no	Container No	Gross wt. (Kg)	Tare wt.(Kg)	Net wt. (Kg)	Weighed by	Checked by	Date
1.							
2.							
3.							
4.							
5.							
6.							
7.							
Total w	eight of Uncoa	ted Tablets (kg)				

Limit: NLT 98.5 %	
Rejected Quantity of Tablets	Kg
Appx. No. of Tablets after inspection (z) =	Total wt. of inspected tablets = Nos.
	Average weight of Tablets
(z) % Yield =	
Non recoverable rejectsKg	Destroyed by
	Checked by (Production)
Checked by	Verified by
Sign & Date:	Sign & Date:
(Production)	(QA)

Prepared By	Checked By		Approved By	
Officer QA	Production Officer Executive QA		Plant Manager DGM-QA	



BATCH MANUFACTURING RECORD

Product: Amlovas 2.5 **Generic Name**: Amlodipine Besilate Tablets

BMR No.: Page 62 of 57

5.0 YIELD RECONCILLIATION

SL. No.	YIELD RECONCILIATION	Weight In kg	Tablets in Numbers
A.	Theoretical Batch Size		
B.	Lubricated granules		
C.	Loss during process (Batch size in kgs. – Lubricated granules in Kgs.)		
D.	Compressed tablets		
E.	Loss during Compression (Lubricated granules wt - Compressed tablets wt.)		
F.	Tablets after inspection		
G.	Loss during inspection		
H.	Quantity of Tablets for Q. C. analysis		
l.	Tablets transferred to packing		
J.	% Yield= <u>I x 100</u> Batch size (Limits: NLT 98.5 %)		
Checked I Sign & Da	by Production te	Checked by QA Sign & Date	

Prepared By	Checked By		Approved By	
Officer QA	Production Officer		Plant Manager DGM-QA	



BATCH MANUFACTURING RECORD

5/11 (11	· // · · · · · · · · · · · · · · · · ·	
Product: Amlovas 2.5	Generic Name: Amlodipine Besilate	e Tablets
BMR No. :	B. No.:	Page 63 of 57

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Prepared By	Checked By		Approved By	
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA



BATCH MANUFACTURING RECORD

Product : Amlovas 2.5 **Generic Name:** Amlodipine Besilate Tablets

BMR No.: Page 64 of 57

REVISION CARD

Sr. No.	BMR No.	Reason for Revision	Effective Date
1	MPL/TAB/BMR/A2 /02	After Validation	01.08.05
2	MPL/TAB/BMR/I-AA /00	Change for Batch no. system and format of BMR	

Prepared By	Checked By		Approved By	
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA