Pharmaguddu.com	

BATCH MANUFACTURING RECORD

Product : Amlovas 2.5	**Generic Name:** Amlodipine Besilate Tablets	
BMR No. :	**B. No.:**	**Page 1 of 57**

Mfg. Date		**Exp. Date**	

Label Claim :
Each uncoated tablet contains:

Amlodipine Besilate BP equiv. to Amlodipine base……..…… 2.5 mg

Colour: Erythrosine supra

Storage Condition: Store in cool, dry place. Protect from light and moisture	**Market:** Domestic **Shelf Life:** 36 Months
Reason for Revision: Change for Batch no. system and format of BMR	**Mfg. Location:** (Tablet Area)
Effective Date:	**Review Period:** Recommendation on the basis of APR
BMR Supersedes No. :	**Product Code:** I - AA
MMF No.:	**Standard Batch size:** 1800,000 Tablets Weight of core tablet: 243.00 kg
Reason for Issue: For Manufacturing	

Contents of Batch Manufacturing Record

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

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 sheets □, 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			
Stores/Date		**Production/Date**	
Balance ID No.	**Checked by**	**Balance ID No.**	**Checked by**

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

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

Date:

Granulation						**Dry mixing (Lot- 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
Binding (Lot –I)												
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.

* 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

NA - Not Applicable

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

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

Date:

Granulation						**Dry mixing (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
Binding (Lot –II)												
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.

* 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

NA – Not Applicable

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

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

Date:

Granulation						**Dry mixing (Lot- III)**						
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
Binding (Lot –III)												
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.

* 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

NA – Not Applicable

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

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

Date:

Extra granular material												
	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.	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.
* Verify gross weight of all the raw material before start of processing (by production officer)
NA – Not Applicable

Raw Material Received By :
(Production) Sign & Date

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

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 □, Equipment log sheets □, Pressure differential of room □**.** Swab test passed □. Swab test analytical 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±2°C and Relative Humidity is 50% ± 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 By		Approved By	
Officer QA	**Production Officer**	**Executive QA**	**Plant Manager**	**DGM-QA**

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 No. 3.1.1 Raw Material Sifting (Lot – I)

Sifting started at: _____ Completed at: _____ Date: _____

Sr. No.	Material	Qty. (kg)	Sieve Size	Sieve Code No.	Sieve Integrity				Done By	Ckd by
					Before	Ckd. by	After	Ckd. by		
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 No. 3.1.2 Raw Material Sifting (Lot – II)

Sifting started at : _____ Completed at: _____ Date: _____

Sr. No.	Material	Qty. (kg)	Sieve Size	Sieve Code No.	Sieve Integrity				Done By	Ckd by
					Before	Ckd. by	After	Ckd. by		
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 No. 3.1.2 Raw Material Sifting (Lot – III)

Sifting started at : _____ Completed at: _____ Date: _____

Sr. No.	Material	Qty. (kg)	Sieve Size	Sieve Code No.	Sieve Integrity				Done By	Ckd by
					Before	Ckd. by	After	Ckd. by		
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 :

3.2.1 Prepare the binder solution as per following procedure for three lots.
3.2.2 Record details in respective tables.

Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-I)

Sr. No.	Operation	Time		Done by	Checked by	Date
		From	To			
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 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

Appearance of solution	**Clear paste**			

Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-II)

		From	To			
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**			

Table No.3.2.1 BINDER SOLUTION PREPARATION RECORD (Lot-III)

		From	To			
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**			

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

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

STAGE 3.3 : DRY MIXING & GRANULATION Date :

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	17.538	17.538
4.	Starch IP	34.344	34.344	34.344
	Done By :			
	Date			
Material Loading	Started At:			
	Completed At			
	Done By :			
	Checked By:			

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

3.3.1.2 Dry Mixing Details

	Date			
		Lot - I	Lot - II	Lot - III
Dry Mixing	**(7 min.)** Started At:			
	Completed At:			
	Done By			
	Checked By			
	Date			

3.3.1.3 Binder solution adding Details(Granulation Record)

	Date			
Granulation	Started At:			
	Completed At:			
Amperage Reading (At the end))point)	Agitator			
	Chopper			
	Done By			
	Checked By			
Amount of extra purified water added Kg				

3.3.1.4 Unloading Details into FBD Bowl

		Lot I		Lot II		Lot III	
Date		Bowl 1	Bowl 2	Bowl 1	Bowl 2	Bowl 1	Bowl 2
Checked by	**Sieve integrity of Bowl**						
	Started At:						
	Completed At:						
	Done By						
	Checked By						

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

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

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

Table No.3.4.1 Drying (Lot-I)

		Bowl : 1		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (^{o}C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
Steam Drying							
Raking							
Steam Drying							
LOD of granules :		**Limit** : NMT 3% w/w at 105°C					

sieve integrity of bowl after drying OK/NOT OK Checked by

FBD bag No	**(FBD bag integrity)**			
	Before drying	**Ckd by**	**After drying**	**Ckd by**

		Bowl : 2		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (^{o}C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
Steam Drying							
Raking							
Steam Drying							
LOD of granules :		**Limit :** NMT3% w/w 105°C					

Sieve integrity of bowl after drying OK/NOT OK Checked by

FBD bag No	**(FBD bag integrity)**			
	Before drying	**Ckd by**	**After drying**	**Ckd by**

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

Table No.3.4.2 Drying (Lot-II)

		Bowl : 1		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (°C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
Steam Drying							
Raking							
Steam Drying							
LOD of granules :			**Limit :** 3% w/w 105°C				
Sieve integrity of bowl after drying		**OK/NOT OK**		**Checked by**			
FBD bag No		**(FBD bag integrity)**					
		Before drying	**Ckd by**	**After drying**	**Ckd by**		

		Bowl : 2		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (°C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
Steam Drying							
Raking							
Steam Drying							
LOD of granules :			**Limit :** NMT 3% w/w 105°C				
Sieve integrity of bowl after drying		**OK/NOT OK**		**Checked by**			

FBD Bag Code no.	(FBD Bag Integrity)			
	Before Drying	Ckd by	After Drying	Ckd by

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

Table No.3.4.3 Drying (Lot-III)

		Bowl : 1		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (^{o}C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
Steam Drying							
Raking							
Steam Drying							
LOD of granules :			**Limit** : NMT 3% w/w 105°C				
Sieve integrity of bowl after drying		**OK/NOT OK**		**Checked by**			

FBD Bag Code no.	(FBD Bag Integrity)			
	Before Drying	Ckd by	After Drying	Ckd by

		Bowl : 2		**Date :**			
Stage	**Time (in min.)**	**Time**		**Temperature (^{o}C)**		**Done By**	**Checked By**
		From	**To**	**Inlet**	**Outlet**		
Air Drying	**5**						
Raking							
team Drying							
Raking							
Steam Drying							
LOD of granules :			**Limit :** NMT3% w/w 105°C0				
Sieve integrity of bowl after drying		**OK/NOT OK**		**Checked by**			

FBD Bag Code no.	(FBD Bag Integrity)			
	Before Drying	Ckd by	After Drying	Ckd by

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

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

Table No. 3.5.1

Date / Lot No & Bowl no	Activity	Screen /sieve size & No.	Screen/Sieve integrity (before use)	Ckd by	Started at	Completed at	Screen /Sieve integrity (after use)	Done by	Checked by
Lot-I (Bowl-1)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							
Lot-I (Bowl-2)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							
Lot II (Bowl-1)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							
Lot II (Bowl-2)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							
Lot III (Bowl-1)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							
Lot III (Bowl-2)	Sifting	_____ (#20)							
	Milling	_____ (2.0mm)							
	Sifting	_____ (#20)							

Ensure that all granules should pass through 20#

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

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						
Theoretical weight-220.67kg			**Total net wt. →**			

% Yield = $\frac{\text{Actual weight}}{\text{Theoretical weight}} \times 100$ **=** **%** **(Limit : NLT 99.5 %)**

Checked by
Sign & Date:
(production)

Verified by
Sign & Date:
(QA)

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

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 No. 3.6.1 Extra Granular Material Sifting

Sifting started at : _____ Completed at : _____ Date: _____

Sr. No.	Material	Qty. (kg)	Sieve Size Code No.	Sieve Integrity Before	Sieve Integrity After	Sieve Integrity Checked by		Started at	Completed at	Done By	Checked by
1.	Dried Starch BP	12.843	60 #								
2.	Sodium Starch Glycollate IP	4.266									
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.

Table No. 3.6.2 **Material loading Record**

From	**Date:**	**Time:**	**To**	**Date:**	**Time:**

Date:	**Quantity**	**From**	**To**	**Done by**	**Checked by**
Lot-I milled granules					
Lot-II milled granules					
Lot-III milled granules					
Dried Maize Starch BP	12.843 Kg				
Sodium Starch Glycollate IP	4.266 Kg				
Purified Talc IP	2.700 Kg				
Colloidal Silicon Dioxide IP	0.900 Kg				

Blending

Blending from _____ to _____ (____minutes) **Date :**

Item	**Quantity**	**Loaded by**	**From**	**To**	**Checked by**
Magnesium Stearate I.P.	1.620 kg				

Final blending from _____ to _____ (____ minutes) **Date :**

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

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

Table No. 3.6.3 Weighing of Lubricated Granules

Balance ID No. : **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%)

% Yield = $\frac{\text{Actual weight}}{\text{Theoretical weight}} \times 100 =$ ---------- x 100 = ---------- %

Checked By (QA)
Sign & Date

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

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 :		**Batch No.**	

TABLET COMPRESSION
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 □, Equipment log sheets □, Pressure differential of room □. Swab test passed □. Swab test analytical report no._____

Sign & Date		
	Checked by (Production)	Approved by (QA)

	COMPRESSION PARAMETERS	
1	**COMPRESSION MACHINE**	**(29 STATION)**
2	**UPPER PUNCH** Size : 7.0 mm Shape : Circular Standard Concave Embossing : A / 2.5	
3	**LOWER PUNCH** Size : 7.0 mm Shape : Circular Standard Concave Embossing : Plain	
4	RPM : 27 ± 3 RPM	
5	• ***Compression should be done at relative humidity of 50 ± 5% and temperature 23± 2 ^{0}C.*** • ***Hopper should always be kept closed***	

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

Table No. 3.7.1 **INPROCESS SPECIFICATION**

S. No.	Parameter	Specification	Frequency		No of tablets Req./side
			Production	QA	
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 ± 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 ± 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 to be collected in primary container. 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 quantity _____kgs Checked by:

Quantity of Tablets destroyed during the first few rounds _____ Nos. Checked by:

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

Table No.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 with the above specification .The above parameters have to be checked by concerned production supervisor and QA officer

Start-up test during tablet compression
Punch inspection details

Note : Enter "√" if punch is complying with the description given in BMR and no damage is seen Enter "X" if punch is not complying with the specification and the damage is seen.

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 done by Production : Sign & Date	Punch inspection checked by QA: Sign & Date

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

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

Table No. 3.7.3 1st Start-up test during tablet compression (Verification of tablet parameters)

Sr. 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 ± 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%)***		

Tablet Parameters checked by Production: Sign & Date	Tablet Parameters checked by QA: Sign & Date

Note : *Theoretical average weight is 135.0 mg*

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

Table No. 3.7.3 2nd Start-up test during tablet compression (Verification of tablet parameters)

Sr. 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 ± 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%)***		

Tablet Parameters checked by Production: Sign & Date	Tablet Parameters checked by QA: Sign & Date

Note : *Theoretical average weight is 135.0 mg*

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

Table No. 3.7.3 3rd Start-up test during tablet compression (Verification of tablet parameters)

Sr. 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 ± 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%)***		

Tablet Parameters checked by Production: Sign & Date	Tablet Parameters checked by QA: Sign & Date

Note : *Theoretical average weight is 135.0 mg*

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

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 :**

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																					

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																					
Sign																					

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

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

Table No. 3.7.4Compression In-process Record (LHS) | **Frequency Every 30 minutes (Production)**

Weight of 40 Tablets : Minimum : 5.292 g, Maximum : 5.508 g **Date :**

Time																					
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5.520																					
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5.460																					
5.445																					
5.430																					
5.415																					
5.400																					
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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																					
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5.370																					
5.355																					
5.340																					
5.325																					
5.310																					
5.295																					
5.280																					
5.265																					
Sign																					

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

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

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 :**

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																					

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																					
Sign																					

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

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

Table No. 3.7.5 **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		

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

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BATCH MANUFACTURING RECORD

Product : Amlovas 2.5	**Generic Name:** Amlodipine Besilate Tablets	
BMR No. :	**B. No.:**	**Page 35 of 57**

Table No. 3.7.5 **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		

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

Table No. 3.7.6 **INPROCESS CHECKS**

Date	Time	Appearance of the tablets Frequency: Every 1 hour (Production)										%	Checked By
		Capping		**Chipping**		**Sticking**		**Broken tablets**		**Discoloration**			
		LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		

Put "X" for nil Rejection

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

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g
Average Weight	
mg	mg
Maximum	
mg	mg
Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g
Average Weight	
mg	mg
Maximum	
mg	mg
Minimum	
mg	mg

Checked by

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

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.7 Limit = 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : PRODUCTION**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Table No. 3.7.8 Compression In-process Record (LHS) | **Frequency Every 1 hour (QA)**

Weight of 40 Tablets : Minimum : 5.292 g, Maximum : 5.508 g **Date :**

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																					

Compression In-process Record (RHS) | **Frequency Every 1 hour (QA)**

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																					

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

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

Table No. 3.7.8 Compression In-process Record (LHS) | **Frequency Every 1 hour (QA)**

Weight of 40 Tablets : Minimum : 5.292 g, Maximum : 5.508 g **Date :**

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																					

Compression In-process Record (RHS) | **Frequency Every 1 hour (QA)**

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																					

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

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

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

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/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 By		Approved By	
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA

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/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 By		Approved By	
Officer QA	Production Officer	Executive QA	Plant Manager	DGM-QA

Table No. 3.7.10 **INPROCESS CHECKS**

Date	Time	Appearance of the tablets Frequency: Every 1 hour (QA)										%	Checked By
		Capping		**Chipping**		**Sticking**		**Broken tablets**		**Discoloration**			
		LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		

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

Put “X” for nil Rejection

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

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g
Average Weight	
mg	mg
Maximum	
mg	mg
Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g
Average Weight	
mg	mg
Maximum	
mg	mg
Minimum	
mg	mg

Checked by

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

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

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

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Uniformity of weight

Table No. 3.7.11 **Limit =** 135.0 mg ± 5.0 % **(Limit** 128.2 mg **to** 141.7 mg**) Frequency : EVERY 2 HOURS : QA**

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Date :
Time :

LHS				RHS			
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.		21.		1.		21.	
2.		22.		2.		22.	
3.		23.		3.		23.	
4.		24.		4.		24.	
5.		25.		5.		25.	
6.		26.		6.		26.	
7.		27.		7.		27.	
8.		28.		8.		28.	
9.		29.		9.		29.	
10.		30.		10.		30.	
11.		31.		11.		31.	
12.		32.		12.		32.	
13.		33.		13.		33.	
14.		34.		14.		34.	
15.		35.		15.		35.	
16.		36.		16.		36.	
17.		37.		17.		37.	
18.		38.		18.		38.	
19.		39.		19.		39.	
20.		40.		20.		40.	

Weight of 40 tablets	
g	g

Average Weight	
mg	mg

Maximum	
mg	mg

Minimum	
mg	mg

Checked by

Table No. 3.7.12		**Weighing record of compressed tablets**			
Balance Identification 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.					
Theoretical weight (kg) =243.00			**Total wt. →**		

Theoretical Weight: 243.00Kg

$$\% \text{ Yield} = \frac{\text{Actual weight}}{\text{Theoretical weight}} \times 100 = \frac{\quad}{\quad} \times 100 = \_\_\_\_\_ \%$$ (LIMIT : NLT 99.0 %)

Samples for QC analysis_____Nos.

Non recoverable rejects _____Kg

Destroyed by _____

Checked by _____(Production)

Verified by _____ (QA)

Checked by(Prod.):
Sign & Date :

Sampling done by (QA)
Sign & Date :

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

4.0 TABLET INSPECTION

TABLET INSPECTION	**Equipment No.**	Operation SOP NO.	**Cleaning SOP No.**
Tablet Inspection Belt Metal Detector	EQ/TAB/XX EQ/TAB/XX	TAB/XYZ TAB/XYZ	TAB/XYZ
Area: Inspection	------	-------	PRD/XYZ

Take Line clearance from QA as per SOP.

Check the following

Area and Equipment cleanliness☐ Removal of Material of previous product/batch,☐ Proper labeling,☐ Completion of BMR/Records☐ Temperature and Relative humidity ☐ Equipment log record ☐ Swab passed ☐ Swab 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

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

DATE/TIME	**Ferrous blocks Embedded with (0.15 mm x 3mm) size of ferrous material**	**Non- Ferrous blocks embedded with (0.2 mmx 3mm) size of non-ferrous material**	**Non Magnetic Steel(SS wire) Embedded with (0.2mm x3mm) size of ss material**	**Done by (Prod.)**	**Checked by (QA)**

Metal detector rejects quantity: _____ Nos _____ Kg_____% (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**

Table No. 4.1	**WEIGHING RECORD of inspected tablet**						
Balance 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 weight of Uncoated Tablets (kg)							

Limit: NLT 98.5 %

Rejected Quantity of Tablets _____Kg

Appx. No. of Tablets after inspection (z) = Total wt. of inspected tablets / Average weight of Tablets = Nos.

% Yield = (z) / Batch size in nos. x 100 = %

Non recoverable rejects _____Kg **Destroyed by _____**

Checked by (Production)

Checked by
Sign & Date:

Verified by
Sign & Date:

(Production) **(QA)**

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

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		
I.	Tablets transferred to packing		
J.	% Yield= $\frac{\text{I x 100}}{\text{Batch size}}$ (Limits: NLT 98.5 %)		
Checked by Production Sign & Date		Checked by QA Sign & Date	

6.0 Process Deviation (If Any):

Production (In-charge) Sign and Date		**QA (In- charge) Sign and Date**	

BMR Checked by

Asst.Manager Production_____ Executive QA:_____

Sign & Date Sign & Date

BMR Verified by

Plant Manager _____ DGM QA _____

Sign and Date Sign and Date

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

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	