PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:116	**Effective Date:**	**Page No.:** 1 of 20
Batch No.: CBR	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets	
Label Claim:	Each uncoated tablet contains: Acarbose IP …….. 25 mg Excipients ……. q.s
Mfg. Lic. No.:	
Product Lic. No.:	**NA**
Self-Life:	____ Months
MFR No.:	
Mfg. Date:	
Exp. Date:	
BMR ISSUED NO.:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 2 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

1.0 MASTER FORMULA:

BILL OF RAW MATERIALS

S. No	Ingredients	Spec.	Qty. In mg Per Tablet	Overages %	Std. Qty. for 1 Lac. In Kg
Raw Material for Dry Mixing					
Active Ingredients-					
1.	Acarbose	IP	25.00	----	2.50#
Inactive Ingredients-					
2.	Starch	IP	40.00	-----	4.00
3.	Microcrystalline Cellulose (Avicel PH 102)	IP	45.00	-----	4.50
4.	Sodium Lauryl Sulphate	IP	10.00	------	1.00
5.	Aerosil (Collidal Silicon Dioxide)	IP	0.50	-------	0.05
Raw Material for Lubrication-					
6.	Talc	IP	0.50	----	0.05
7.	Magnesium Stearate	IP	0.50	----	0.05
8.	Sodium Lauryl Sulphate	IP	9.50	-----	0.95
9.	Croscarmellose Sodium	IP	5.00	-----	0.50
10.	Aerosil (Collidal Silicon Dioxide)	IP	0.50	-----	0.05
	Weight of Uncoated Tablets		**136.50 mg**		**13.65 Kg**

Note: # Acarbose IP adds after calculation if assay below 95%.

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 3 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

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

Note: If assay of API is above 95.0% calculation not required.

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

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

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

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

PART B: To be calculated when more than one A.R. No. of **Acarbose IP** is to be used:

A.R. No. of Acarbose IP	**Assay on as such basis (A1)**	**Actual quantity Available (b1) (Kg)**	**Qty. on 100 % assay basis = (b1) x (a1) ---------- Kg 100**	**Remaining qty. to be dispensed (e1) = Std. qty. -(c1)**
				(e1) = _____# - _____ = _____ Kg
TOTAL (Kg) ---		_____	(c1)=_____	

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

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

Therefore total quantity of **Acarbose** IP to be dispensed = (b1) + (g1) =_____Kg

Assay calculation:

Sign/ Date		
Department	**Done by (Production)**	**Checked by (QA)**

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

	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 4 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

2.0 GENERAL INSTRUCTIONS:

- Current version of SOPs should be referred during operation.
- Dispensed raw material/bulk blend/ compressed tablets should be manufactured and stored at temperature not exceeding 27°C and RH NMT 55%
- In all the processing activities, nose mask, hand gloves, secondary gown etc. shall be weared by the personnel.
- Attach all dispensing tags and cleaning status labels with BMR.
- Clean the equipment's after use as per the standard operating procedure.
- The Blend should be compressed within 15 days.
- The compressed tablets should be packed within 30days.
- Follow cGMP during entire manufacturing.
- Verifying the product name, B.No., batch size, ingredients at the time of product handling.

2.1 Line clearance of Dispensing:

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

S.No.	Instructions	Yes/No/NA
1.	Is dispensing area clean and free from any materials of previous batches?	
2.	Whether balance is calibrated and have status label.	
3.	Scoops to be used for dispensing are clean.	
4.	LAF properly working and dispensing booth clean.	
5.	Air differential pressure, temperature and humidity with in limit (if applicable) Temp. ---------- ºC (NMT 27ºC), RH----------% (NMT 55.0%), DP……..(0.5to1.5P or in mm of H_2O)	
6.	Material shall be least exposed to atmosphere.	
7.	Ensure proper gowning before entering to the dispensing area, suitable nose mask and surgical gloves shall be used while handling the material.	

Previous product name:_____	**Batch No.: _____**
Differential pressure across RLAF and Room: _____	(Limit(Between 5 to 15 Pascal)

Checked By (Production): **Sign & Date:**		**Verified By (IPQA):** **Sign & Date:**	

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 5 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

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

S. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
					Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-										
Active Ingredients-										
1.	Acarbose	2.50#								
Inactive Ingredients-										
2.	Starch	4.00								
3.	Microcrystalline Cellulose (Avicel PH 102)	4.50								
4.	Sodium Lauryl Sulphate	1.00								
5.	Aerosil (Collidal Silicon Dioxide)	0.05								
Raw Material for Lubrication-										
6.	Talc	0.05								
7.	Magnesium Stearate	0.05								
8.	Sodium Lauryl Sulphate	0.95								
9.	Croscarmellose Sodium	0.50								
10.	Aerosil (Collidal Silicon Dioxide)	0.05								

Note: # Acarbose IP adds after calculation if assay below 95%.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:		**BMR No.:**
Product Name:		**Generic Name:** Acarbose Tablets IP 25 mg
Document No.:	**Effective Date:**	**Page No.:** 6 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

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

S. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
					Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-										
Active Ingredients-										
1.	Acarbose	2.50#								
Inactive Ingredients-										
2.	Starch	4.00								
3.	Microcrystalline Cellulose (Avicel PH 102)	4.50								
4.	Sodium Lauryl Sulphate	1.00								
5.	Aerosil (Collidal Silicon Dioxide)	0.05								
Raw Material for Lubrication-										
6.	Talc	0.05								
7.	Magnesium Stearate	0.05								
8.	Sodium Lauryl Sulphate	0.95								
9.	Croscarmellose Sodium	0.50								
10.	Aerosil (Colloidal Silicon Dioxide)	0.05								

Note: # Acarbose IP adds after calculation if assay below 95%.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 7 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

2.2 Weighing sheet:

Balance ID: _____

S. No.	Ingredients	Spec.	UOM	Std. Quantity (Kg)	A.R. No.	Issued Qty			Checked By (Prod.)	Verified by (IPQA)
						Gr. wt.	Tare wt.	Net wt.		
MATERIAL FOR GRANULATION:										
1.	Acarbose	IP								
2.	Starch	IP								
3.	Microcrystalline Cellulose	IP								
4.	Sodium Lauryl Sulphate	IP								
5.	Aerosil (Collidal Silicon Dioxide)	IP								
MATERIAL FOR LUBRICATION:										
6.	Talc	IP								
7.	Magnesium Stearate	IP								
8.	Sodium Lauryl Sulphate	IP								
9.	Croscarmellose Sodium	IP								
10.	Aerosil (Collidal Silicon Dioxide)	IP								

3.0 MANUFACTURING PROCESS: **Started on:**_____

3.1 Line clearance:

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

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

S. No.	Instructions	Yes/No/NA	Checked By (Production)	Verified By (IPQA)
1	Ensure that all equipment and utensils are clean and dry.			
2	Is area free from any materials of previous batch?			
3	Whether the container, sieve, scoops and auxiliary items are cleaned.			
4	Check the room temperature. Temp……..ºC (NMT 27ºC) and Differential pressure ……. Pascal (0.5to 1.5 Pascal or in mm of H_2O).			
5	Follow cGMP in all time process			
6	Calibration status of Equipment/instrument complies or not.			
7	Balance calibration and verification is OK or not.			
8	Whether swab/rinse sample testing report complies or not? (if applicable)			
9	Whether the wall, floor and light in satisfactory condition?			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 8 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

Note: Verify the materials as per product BOM during receipt and at time of addition.

EQUIPMENT STATUS CHECKLIST

S. No.	Name of Equipment	Equipment ID No.	Observation (Should be clean and dried)	Checked (Production)	Verified By (IPQA)
1.	Sifter		Yes/No		
2.	Mass mixer		Yes/No		
3.	Blender		Yes/No		
4.	Multi mill		Yes/No		
5.	Balance		Yes/No		
6.	SS Scoop		Yes/No		

3.2 Sifting of Raw Materials: Sift separately the following material and collect in poly bags/containers.

SIFTING OF DRY MIXING MATERIALS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd. By/ Date
			Before Use	After use				
Acarbose IP		40#						
Starch IP		40#						
Microcrystalline Cellulose IP		40#						
Sodium Lauryl Sulphate IP		40#						
Aerosil IP		40#						

SIFTING OF LUBRICATING MATERIALS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd By/ Date
			Before Use	After use				
Talc IP		60#						
Aerosil (Collidal Silicon Dioxide) IP		60#						
Sodium Lauryl Sulphate IP		60#						
Cross Carmellose Sodium IP		60#						
Magnesium Stearate IP		60#						

Note: Check sieve integrity before and after use.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 9 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

Step No.	Manufacturing Instruction	Eq. ID. No.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Dry Mixing:**					
	Load **Acarbose (**____#Kg**), Starch (**____ Kg**), Microcrystalline Cellulose (Avicel PH 102) (**____Kg**), Sodium Lauryl Sulphate (**____Kg) and **Aerosil (**_____Kg) in a mass mixer and run at slow speed for 10 minutes. Collect the granules in a clean polybags and send it for slugging.					

3.3.2 Slugging of dry mix material:

Line clearance of compression M/C for slugging: **Slugging Started At: _____**

Previous product: _____, Batch No.:_____

Cleaning done by: _____, Cleaned On: _____,

S. No.	Instructions	Yes/No/NA	Checked By (Production)	Verified By (IPQA)
1	Is area free from any materials of previous batch?			
2	Whether area and utensils cleaned?			
3	Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? Equipment ID No.: _____			
4	Check the room temperature, RH and differential pressure =……ºC (NMT 27ºC), RH=…… % (NMT 55%). Differential Pressure……..mm of H_2O (0.5to 1.5 mm of H_2O)			

Table: A-Die and punch verification

Punch Specification			
Punch Details	Type	B Tooling & ___ Station	
	Upper Punches	11 mm	Dies: 11.1 mm
	Lower Punches	11mm	

Note: Hardness of the tablets as per requirement and collect the slugged in a clean poly bags.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 10 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

Step No.	Manufacturing Instruction	Eq. ID. No.	From	To	Done By/ Date	Ckd. By/ Date
3.3.3	**Milling & Sifting of slugged materials:**					
	Milling the slugged tablet through milt mill at 750 RPM through **0.5 mm** screen					
	Again pass the milled materials through **80#** sieve and then collected in cleaned poly bags.					
3.3.4	**Lubrication:**					
	Load **Talc** (____Kg), **Sodium Lauryl Sulphate** (____Kg), **Crosscarmellose Sodium** (____Kg) and **Aerosil** (___Kg) in blender with sifted granules from stage 3.3.3 and mix it for 10 minutes.					
	Add **Magnesium Stearate** (____Kg) in blender and mix it for further for 2-3 minutes.					
3.3.5	Send intimation form to QC department for testing.					

4.0 SAMPLING OF BLEND:

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

_____
Checked By (Production)

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

_____
Checked By (IPQA)

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

BLEND WEIGHING RECORD

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

	Prepared By	Checked By	Approved By
Signature			
Date			

4.1 YIELD RECONCILIATION:

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

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

C = Samples = ….. ……..

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

Loss Quantity: _____

Checked by (Production):
Date:

Verified by (QA):
Date:

5.0 COMPRESSION:

Date: _____ **Started At: _____**

5.1 Line clearance:

Previous product: _____, Batch No.:_____

S. No.	Instructions	Observations	Checked (Production)	Verified By (IPQA)
1.	Is area free from any materials of previous batch?	Yes/No		
2.	Whether area and utensils cleaned?	Yes/No		
3.	Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? Equipment ID No.: _____	Yes/No		
4.	Check the room temperature, RH and differential pressure =……ºC (NMT 27ºC), RH=…… % (NMT 55%). Differential Pressure……..mm of H_2O(0.5to 1.5 mm of H_2O)	OK/NOT OK		
5.	All the equipment shall be used during process are cleaned.	Yes/No		

5.2 Process:

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

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

Table: A-Die and Punch verification

Punch Specification																								
Punch Details	Type	B- Tooling & __ Station																						
	Upper Punches	7.1 mm (Round shape with break line)																					Dies : 7.2 mm	
	Lower Punches	7.1 mm (Round shape plain)																						
Upper Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											
Lower Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											

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

5.3 IN PROCESS CHECKS:

5.3.1 Specification:

S.No.	Parameters	Requirement	Frequency of Monitoring
1.0	Description	White or off white colour round shape biconvex tablets with one side break line.	At the start of machine
2.0	Weight of 20 tablets	2.73 gm ± 3%	Every 30 Minutes
3.0	Avg. weight	136.50 ± 3%	Every 2 Hours
4.0	Uniformity of weight	136.50 ± 7.5%	Every 2 Hours
5.0	Thickness	___ ±0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3 Kg/cm^2	Every 2 Hours
7.0	Friability	NMT 1%	Every 2 Hours
8.0	DT	NMT 15 min	Every 2 Hours
9.0	Diameter	7.2 mm	At the start of machine
10.0	Temperature	NMT 27 ° C	Every 2 Hours
11.0	RH	NMT 55%	Every 2 Hours

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 14 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

5.4 In-process observation sheet for production:

Description:											
Diameter:											
Wt. of 20 Tabs. 2.73 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 2.73 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness ____ ±0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT ____ Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White or off white color round shape biconvex tablets with one side break line.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required…

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

WEIGHT VARIATION OF 20 TABLETS

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

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

Attached additional sheet if required…….

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 16 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

5.5 In-process observation sheet for IPQA

Description:											
Diameter:											
Wt. of 20 Tabs. 2.73 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 2.73 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness ___ ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min.	LHS										
	RHS										
Appearance: White or off white colour round shape biconvex tablets with one side break line.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required……..

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 17 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

WEIGHT VARIATION OF 20 TABLETS

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

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

Attached additional sheet if required……..

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 18 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

6.0 TABLET WEIGHING RECORD:

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

7.0 SAMPLING:

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

_____
Checked By (Production)

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

_____
Checked By (IPQA)

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

7.1 YIELD RECONCILIATION:

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

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

Loss Qty.: _____ Kg.

	Prepared By	Checked By	Approved By
Signature			
Date			

8.0 VISUAL INSPECTION OF TABLET:

Date: _____

Time Duration		Quantity rejected	Done by
From	To		

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

% Yield: _____

Checked by (Production): _____, **Verified by (IPQA): _____**
(Sign & Date) **(Sign & Date)**

9.0 SAMPLING:

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

_____
Checked By (Production)

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

_____
Checked By (IPQA)

9.1 YIELD RECONCILIATION:

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

	Prepared By	Checked By	Approved By
Signature			
Date			

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Acarbose Tablets IP 25 mg	
Document No.:	**Effective Date:**	**Page No.:** 20 of 20
Batch No.:	**Batch Size:**	**Supersedes No.:**

10.0 FINAL REVIEW OF BATCH CARD ON SHOP FLOOR:

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

_____

Checked By (Prod. Mgr.)

11.0 ANY DEVIATION:

Deviation No.	Reason for deviation

_____

Checked By (Prod. Manager)

12.0 HISTORY SHEET:

BMR No.	New BMR No.	Revision No.	Reason of revision

	Prepared By	Checked By	Approved By
Signature			
Date			