

PHARMA DEVILS ____

	PHAKMADEVILS					
	PRODUCTION DEPARTMENT					
	ВАТ	CH PACKIN	G RECORD			
Product Code:			BPR No.:			
Product Name:			Generic Name: Acarbose	e Tablets IP 25 mg		
Effective Date:				Page No.: 1 c	of 23	
Batch No.:			Batch Size:	Supersedes N	Io.: Nil	
		ALU	-ALU PACKING			
Location:						
Block: Productio	on Tablets (PT)					
	Each un	coated tablet con	itains:			
Label Claim:	Acarbos	e IP	25 mg			
Laber Claim.		ıts	-			
Mfg. Lic. No.:						
Product Lic. No	.: NA					
Self-Life:	mo	onths				
Pack Style:	10 x 10	Fablets				
Country Name:	Domesti	с				
Change Control	No.: NA					
Mfg. Date:						
Exp. Date:						
BMR ISSUED N	NO.:					
MRP:						
		Issued	By Stamp & Sign.	1		
			FF	_		
Responsibility	Nar	no	Designation	Sign	Date	
Prepared By	INAL		Designation	Sign	Date	
Checked By						
Approved By						



PRODUCTION DEPARTMENT

Product Code:	BPR No.:	
Product Name:	Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:		Page No.: 2 of 23
Batch No.:	Batch Size:	Supersedes No.: Nil

1.0 GENERAL INSTRUCTIONS:

- Sood manufacturing practices should be followed during the entire process of packing.
- > All the Equipments used for packing should be properly cleaned as per the relevant SOP.
- All the Equipments and containers should have proper status label with Stage, Product name, B. No., Mfg. Date etc.
- > All the equipments should be operated as per the relevant SOP's only.
- Issued packing materials should be cross checked by production personnel against dispensing sheet before taking up for packing.
- > Overwriting in BPR shall be strictly avoided & correcting shall be made as per SOP.
- All the activities should be carried out according to the BPR only. All the operations shall be carried out in clean and orderly manner.
- Any deviation in process shall be bought to knowledge of QA and prior approval of QA department should be taken.
- > Critical parameters like temperature, Humidity and pressure differences should be checked and monitored.
- In process controls should be carried out throughout the packing operations as per relevant BPR and relevant SOP's.
- Ensure that all the packing materials, in process materials and finished goods should be placed in respective areas with proper label to avoid mix up.
- > Attach additional issue sheets from QA, wherever required.
- > Attach system generated data sheets wherever applicable.

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

	BATCH PACKING	RECORD	
Product Code:		BPR No.:	
Product Name:		Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:			Page No.: 3 of 23
Batch No.:		Batch Size:	Supersedes No.: Nil

2. DISPENSING OF PACKING MATERIALS:

2.1Instructions:

- 1. Follow the packing materials dispensing SOP.
- 2. Appropriate weighing balances should be used while issue.
- 3. Ensure that weighing balances are calibrated & Verified on daily basis.
- 4. Printed Al. Foil and Special /PVC should be issued in poly bags.
- 5. Each roll should be labeled separately.
- 6. Cartons should be issued in bundles.
- 7. Cartons should be kept in plastic/shippers crates covered with lid or supplier and properly labeled.
- 8. Carton should be closed with transparent Cello tape.
- 9. One complaint slip is pasted on inside flap of corrugated box.
- 10. Shippers should be issued in bundles with proper label.
- 11. Keep all issued materials on separate pallets in PM dispensing room.

2.2 Line Clearance Checks:

S.No.	Line Clearance Checks	Observation	Checked by QA
1.	Containers used for previous batch/product removed from area		
2.	All status labels of previous batch/products are removed		
3.	BPR or any other documents related to the previous batch / product are removed from area.		
4.	Absence of any previous product /batch remnants		
5.	Cleanliness of the area		
6.	Cleanliness of the area below balances/ pallets.		

2.3 Line clearance certificate for area and equipment:

Area	PM dispensin	g room	Equipment	Weighing Balance
Area Cleaned By:			Equipment No.:	
Checked By:			Equipment Cleaned By:	
Previous Product:			Batch No.:	
Checked By (Packing Su Sign & Date	pervisor):			
Line clearance Given By Sign & Date	(IPQA):			

	Prepared By	Checked By	Approved By
Signature			
Date			

Date: _____



BATC	CH PACKING RECORD	
Product Code:	BPR No.:	I
Product Name:	Generic Name: Acarbo	ose Tablets IP 25 mg
Effective Date:		Page No.: 4 of 23
Batch No.:	Batch Size:	Supersedes No.: Nil

2.4 BILL OF PACKING MATERIALS:

(BPR Copy)

Date: _____

S. No.	Items	Std. Qty. for 1 Lac. in	#Required Qty.	Issued Qty. In	A.R. No.	Issued by	Check	ed By
110.		Kg/Nos.	In Kg/Nos.	Kg/Nos.		Store	Prod.	QA
1	Printed Aluminium Foil , Foil Width = 212 mm	4.00 Kg						
2	Base Foil- Cold form Alu-Alu foil, Foil Width = 212 mm	15.00 Kg						
3	Carton - Dim: 105 X 45 X 48 mm (10x10 Tabs.)	1000 Nos.						
4	5 PLY CORRUGATED BOX- Dim (OD): 465 (L) x 435 (W) x 255(H) mm, (200 Cartons per box 10x4x5) Mkt.by address is printed in corr. box length panel in red colour.	5 Nos.						
5	BOPP TAPE - BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						
6	Cello tape ½ inch	02 Nos.						

Note- Material which is not required cut it.

Calculate the materials as per required batch size.

Dispensed (Store)		Checked By: rod. Supervisor)	Verified By: (QA)
	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING		
Product Code:	BPR No.:	
Product Name:	IP 25 mg	
Effective Date:		Page No.: 5 of 23
Batch No.:	Batch Size:	Supersedes No.: Nil

BILL OF PACKING MATERIALS

(STORE COPY)

Date: _____

Store copy page No.: 5 of 23

S. No.	Items	Std. Qty. for 1 Lac. in	#Required Qty.	Issued Qty. In	A.R. No.	Issued by	Check	
		Kg/Nos.	In Kg/Nos.	Kg/Nos.		Store	Prod.	QA
1	Printed Aluminium Foil , Foil Width = 212 mm	4.00 Kg						
2	Base Foil- Cold form Alu-Alu foil, Foil Width = 212 mm	15.00 Kg						
3	Carton - Dim: 105 X 45 X 48 mm (10x10 Tabs.)	1000 Nos.						
4	5 PLY CORRUGATED BOX- Dim (OD): 465 (L) x 435 (W) x 255(H) mm, (200 Cartons per box 10x4x5) Mkt.by address is printed in corr. box length panel in red colour.	5 Nos.						
5	BOPP TAPE - BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						
6	Cello tape ½ inch	02 Nos.						

Note- Material which is not required cut it.

Calculate the materials as per required batch size.

Dispensed (Store)		Checked By: od. Supervisor)	Verified By: (QA)
	Prepared By	Checked By	Approved By
Signature			
Date			



PHARMA DEVILS PRODUCTION DEPARTMENT BATCH PACKING RECORD

Product Code:	BPR No.:	
Product Name:	Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:		Page No.: 6 of 23
Batch No.:	Batch Size:	Supersedes No.: Nil

3.0 PACKING SPECIFICATION:

S. No.	Description	n Over Printing Matter Standards Over Printing Matter Act (For Example only)		Printing Matter Actual	Check	-	
)		Prod.	QA	
A.	Primary Packi						
1.	ALU-ALU Blis	ter:	1		1		
	Alu-Alu Blister coding details	B. No MFG EXP M.R.P.Rs PER 10 TABS. INCL.OF ALL TAXES					
B. Secondary Packing:							
	Carton	Printed	Carto	n details: 10x10 Tablets			
1.	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Tablets					
C.	Tertiary Packi	ng					
	5 ply Shipper	5 ply printed shipper					
	Shipper details	200 cartons in one 5 ply shippe	r				
1.	Shipper coding details	TABLETS B.No MFG EXP Qty. 200 X 10X10 TABS.					
Sealing of Shipper/BOPP Printed BOPP Tape in "H" type on top and bottom. Tape							
Sigr	nature	Prepared By	Checked B	y Appr	oved By		
Dat	e						



Batch No.:

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH PACKING RECORD Product Code: BPR No.: Product Name: Generic Name: Acarbose Tablets IP 25 mg Effective Date: Page No.: 7 of

	Page No.: 7 of 23
Batch Size:	Supersedes No.: Nil

3.1 STANDARD PACKING INSTRUCTIONS:

- Check and verify the status board/label.
- All the materials of previous batches should be removed and line clearance certificate to be obtain from IPQA before starting any activity.
- Transfer the QC Released Tablets of the Batch to the primary cubicle.
- Produce the blister of 1x10 tablets using 212 mm printed aluminum foil & 212 mm base foil on a blister packing machine. The blister should be duly overprinted with the respective batch legend.
- Blister sealing leak test should be performed periodically to monitor the sealing.
- Each Blister should be visually inspected to reject the defective ones.
- 10x10 tablets such inspected blisters should be packed inside each printed carton. The carton should be duly overprinted with the respective batch legend.
- 200 such inspected unit carton should be packed inside the each shipper.
- The shipper should be properly labeled using coder. The coding details should be overprint with the respective batch legend on the shipper label.
- Each shipper should be sealed using Pre-printed BOPP tape in "H" type on top and bottom.
- After completion of the batch packing, intimate IPQA department through the transfer ticket.
- Complete the BPR for reconciliation of the batch after that transfer the packed shippers to the Finish Goods Store.

3.2 PACKING -

Instructions:

- a. Gowning should be follows as per SOP.
- b. Masks and gloves should be used in the primary packing.
- c. Check for the cleanliness of the area and equipment.
- d. Check the Temperature, Humidity, and differential Pressure as per BPR or as per SOP
- e. Check that batch/product is released by QC for packing before starting of packaging operations and transfer to primary packing.
- f. Check the status label on the area on the display board outside the packing cubical.
- g. Operate Alu-Alu blister packing machine as per SOP.
- h. Line clearance should be given take during any shift change.
- i. Line clearance procedure should also be followed in case of change in stereo or any major breakdown which can affect the packing quality.

	Prepared By	Checked By	Approved By
Signature			
Date			

Date:



	BATCH PACKING	RECORD	
Product Code:		BPR No.:	
Product Name:		Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:			Page No.: 8 of 23
Batch No.:		Batch Size:	Supersedes No.: Nil

3.3 Line clearance check (Initial/shift change over):

Please Tick $\sqrt{If Yes \& X If No or Not Applicable}$ Line Clearance of Packing Line

	Ç		-				1	
S.No.	Clearance Checks	Date						
5.110.	Creatance Checks	Time						
1.	Product name: TAB	LETS						
2.	Area Cleanliness below/ Balance/ atc.	Pallets/						
3.	Machine Cleanliness							
4.	Packaging material of previous pro remove.	duct						
5.	Over coding details on Blisters							
6.	Over coding details on unit carton							
7.	Pasting cello tape							
8.	Over coding details on outer carton							
9.	Product Packaging Insert							
10.	Specimen of 5 Ply Shipper coding							
11.	Correctness of status label							
12.	Daily Verification of balances							
Check	ed by Production (Sign/Date)							
Verifie	ed by IPQA (Sign/Date)							

3.4 Verification of tablet received from core area:

Total Container No.	Total Weight	Checked by Production	Verified by IPQA

3.5 Stereo detail:

Issue the required number of stereos to operator and retrieve the same from them after completion of activity and record shall be maintained as per table given below;

	f Stereos I from QA		ereos given perator	retur	f Stereos rned by erator		. of Stereos ted to QA	Submitted by (Packing)	Retrieved By (IPQA)
Carton	Blister	Carton	Blister	Carton	Blister	Carton	Blister		

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

	BATCH PACKING	RECORD	
Product Code:		BPR No.:	
Product Name:		Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:			Page No.: 9 of 23
Batch No.:		Batch Size:	Supersedes No.: Nil

3.6 Line clearance overprinting of carton:

- i. Line clearance of the area and machine.
- ii. Affix the specific batch stereo and prepare a specimen proof for the approval of packing supervisor and then by IPQA supervisor & affix in the BPR.
- iii. After approval start coding of carton and check the each carton for correctness and legibility of the batch detail.
- iv. In-process, rejection and destruction of rejected cartons shall be recorded.

Line clearance certificate for area and equipment					
Area:	Equipment:	Carton coding machine			
Area Cleaned By:	Equipment No.:				
Checked By:	Equipment Cleaned By:				
Previous Product:	Batch No.:				
Checked By (Packing Supervisor): Sign & Date					
Line clearance Given By (IPQA): Sign & Date					

Over coding detail for Blister, Carton and Shipper

S.No.	Over printin	g details	Blister	Outer Carton	Shipper
	Details on PM (for example)	Actual details	(ALU-ALU)		
1.	TABLETS				
2.	Batch No.:				
3.	Mfg. Date:				
4.	Exp. Date:				
5.	M.R.P.: (Incl. of all taxes) Per 10 Tablets				
6.	Qty. 200 x10 x 10 TABS				
Dealstree	Signature				
Packing	Date				
ШОА	Signature				
IPQA	Date				

Note: Which is not applicable mention NA and put tick mark which is applicable.

	Prepared By	Checked By	Approved By
Signature			
Date			



	BATCH PACKING	RECORD	
Product Code:		BPR No.:	
Product Name:		Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:			Page No.: 10 of 23
Batch No.:		Batch Size:	Supersedes No.: Nil

3.7 Reconciliation of Packing Material:

S. No.	Particulars	Particulars Outer Cartons					
1.	Quantity Issued						
2.	Quantity coded						
3.	Good inspected quantity						
4.	Quantity rejected						
5.	Qty. destroyed						
6.	Qty. destroyed by						
Check	Checked by Prod. (Sign/Date)						
Verifi	ed by IPQA (Sign/Date)						

3.8 Shipper coding:

- Arrange the klass marker of respective batch no. for coding on unit carton and arrange the alphabets for i. shipper label coding as per information given in the BMR and first take a specimen on carton and shipper label coding specimen on plain A4 size paper & get the approval from packing supervisor and then from IPQA.
- ii. After approval all the unit carton/shipper of the batch shall be coded and if any unit carton/shipper rejected during coding same shall be destructed and record shall be maintained.

ALU-ALU: 4.0

Machine Setting: 4.1

1. Take line clearance from IPQA.

Line clearan	ce certificate for area and equip	oments:		
Area	Equipment	ALU-ALU Machine		
Area Cleaned By	Equipment No.			
Checked By	Equipment Cleaned By			
Previous Product	Batch No.			
Checked By (Packing Supervisor): Sign & Date				
Line clearance Given By (IPOA): Sign & Date				

Jiven By (IPQA): Sign & лп

- 2. Check the change parts as per product specification.
- 3. Mount the rollers and check the cavity alignment of sealing roller.
- 4. Mount BCP, and affix stereos.
- 5. Adjust forming & sealing temperature and pressure.
- 6. Load the printed and plain foil, and adjust machine to smooth foil run and take out proof of batch coding. Get the approval from packing supervisor and IPQA.
- 7. Set the sealing temperature 180°C to 200°C. Forming Temp. 150°C to 160°C.
- 8. Ensure proper Knurling and cutting length.
- Check status label on Tablets containers. 9.

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING	RECORD	
Product Code:	BPR No.:	
Product Name:	Generic Name: Acarbose Tablets	IP 25 mg
Effective Date:		Page No.: 11 of 23
Ratch No ·	Batch Size	Supersedes No · Nil

- 10. Load the hopper with Tablets to be stripped.
- 11. Operate the Alu-Alu blister packing machine as per SOP.
- 12. Check the leak test of blister as per Leak Test SOP. Record it in in-process control record.
- 13. Attach approved specimen sample to BPR duly signed by Packing Supervisor and QA Personnel.

4.2 General instruction:

- 1. Carry out blistering operation after batch printing approval by production supervisor & IPQA.
- 2. Record the parameters at a stated frequency.
- 3. Carry out the Leak test as per SOP.
- 4. Note the changes in foil rolls and splices.
- 5. Check the coding on each splice and foil at the start and end. Check at least 1 meter section of each side.
- 6. Foil rolls / Splices should be numbered.
- 7. Attach the sample of every new foil roll and every splice in each roll with BPR.
- 8. Note the Machine start, stop and end time.

4.3 Alu-Alu Packing Start up Control Checks:

- 1. Run the machine and collect few initial Blisters.
- 2. Check for Knurling, Cutting, sealing, batch overprinting, etc. and observation shall be recorded.
- 3. If the initial parameters are satisfactory, continue packing.
- 4. In process test observation shall be recorded both by packing and IPQA supervisor as per table No.4.4
- 5. Reasons for machine stop should be recorded. In the following tables.

4.4 Secondary and tertiary packing:

- 1. Pack the number of Blister in carton then followed by outer carton and finally in shipper as per requirement given in section 2.0 (packing specification).
- 2. Each carton and shipper shall weigh to identify the shortage if any.
- 3. Close the shipper by BOPP tape properly.
- 4. Person involve in the packing shall be recorded as per following table:

Date				
Time	То	То	То	То
Inspection of Blist	er done by			
Counting of Bliste	r done by			
Carton printing ch	ecked by			
Insertion of Blister done by	r & Carton			
Inspection of over carton done by	coding on			
Shipper coding do	ne by			
Insertion of Cartor done by	n in shipper			
	Duenened Dr	Cheeleed De		Ammuned Der

	Prepared By	Checked By	Approved By
Signature			
Date			



· 7	-					TON D								
		B	ATCH	PACKI	ING R	ECO	RD							
Prod	uct Code:				1	BPR N	lo.:							
Prod	uct Name:				(Gener	ic Nam	e: Acar	bose Ta	blets I	P 25 mg			
Effec	tive Date:										Page No).: 12 o	f 23	
Batcl	h No.:]	Batch	Size:				Superse	edes No	.: Nil	
	per sealed ar	nd weighed l	ру											
	cked by													
	luction/pack	king												
IPQ	A													
5.0 I	N PROCES 5.1 In	S CHECK: -process ch	eck by p	roductio	on at iı	nitial a	nd ever	y 30 mi	n.					
S.	In process	Date												
No.	checks	Time												
1.	Temp.													
2.	RH													
3.	Forming ro													
	temperature Sealing rol													
4.	Temperatur													
5.	Check wor NFD by rea one tablet f track	moving												
6.	Tab. with f black partic													
7.	Foil shiftin	g												
8.	Batch detai	l on foil												
9.	No. of tab/													
10.	Proper cutt Blister	ing of												
11.	Leak test (l													
12.	Proper glui carton	-												
13.	No. of Blis printed car	ton												
14.	Batch detai	ton												
15.	Seal the car cello tape													
16.	snipper													
17.	Batch detai shipper lab	el												
18.	U	_									_			<u> </u>
Checl	ked by (Proc	luction)												

	Prepared By	Checked By	Approved By
Signature			
Date			



		PRODUCTION DEPARTMENT											
		B	АТСН Р	ACKIN	G RECO	RD							
Prod	uct Code:				BPR I	No.:							
	uct Name:						e: Acar	bose Tabl	ets IP 2	5 mg			
	tive Date:								1		: 13 of	23	
	1 No.:				Batch	Size:					les No.		
										<u>r </u>			
		I	n-process	s check by	y producti	ion at ini	tial and	l every 3() min.				-
S.	In process	Date											
No.	checks	Time											
1.	Temp.												
2.	RH												
3.	Forming ro temperatur												
4.	Sealing rol												
	Temperatu Check wor												
	Check wor NFD by rea												
5.	one tablet f												
	track												
6.	Tab. with f												
7.	black partie Foil shiftin												
8.	Batch detai	-											
8. 9.	No. of tab/												
	Proper cutt												
10.	Blister	ing or											
11.	Leak test (Hourly)												
12.	Proper glui carton	ng of											
13.	No. of Blis												
	printed car Batch detai												
14.	printed car												
15.	Seal the ca	rton with											
	cello tape No. of cart	on in on-						+				-	
16.	No. of cart shipper	on in one											
17.	Batch detail												
18.	Pasting of												
Check	xed by (Proc	duction)											
·								· ·					
		P	repared	Bv		Che	cked B	V		A	oprove	d Bv	
				J				J		1			
Sign	ature												
Date	e –												



S.

1.

2.

3.

4.

5.

6.

7.

8. 9.

10.

11.

12.

13.

14.

15.

16.

17.

18.

cello tape

shipper

No. of carton in one

Pasting of BOPP tape

Batch details on

shipper label

Checked by (Production)

No.

PHARMA DEVILS

PRODUCTION DEPARTMENT **BATCH PACKING RECORD Product Code: BPR No.: Product Name:** Generic Name: Acarbose Tablets IP 25 mg **Effective Date:** Page No.: 14 of 23 **Batch No.: Batch Size:** Supersedes No.: Nil In-process check by production at initial and every 30 min. Date In process checks Time Temp. RH Forming roller temperature Sealing roller Temperature Check working of NFD by removing one tablet from each track Tab. with foreign / black particle Foil shifting Batch detail on foil No. of tab/ Blister Proper cutting of Blister Leak test (Hourly) Proper gluing of carton No. of Blister in one printed carton Batch detail on printed carton Seal the carton with

	Prepared By	Checked By	Approved By
Signature			
Date			



				PRODU	CTION D	EPARTM	INT					
		BA	TCH PACI	KING	RECO	RD				-		
Prod	uct Code:				BPR N	No.:						
Prod	uct Name:				Gener	ic Nam	e: Acar	bose Tablet	s IP 25 m	g		
Effec	ctive Date:								Page 1	ge No.: 15 of 23		
Batc	h No.:				Batch	Size:			Super	sedes No.	.: Nil	
		In	n-process che	ck by j	producti	on at ini	itial and	d every 30	min.			
S.	In process	Date										
No.	checks	Time										
1.	Temp.											
2.	RH											
3.	Forming rol											
	temperature Sealing roll											
4.	Temperatur											
	Check working of											
5.	NFD by ren one tablet fi											
	track											
6.	Tab. with fo											
	black partic										<u> </u>	
7.	Foil shifting											
8. 9.	8. Batch detail on foil											
	Proper cutting of											
10.	Blister	ing of										
11.	Leak test (Hourly)											
12.	Proper gluir carton	ng of										
13.	No. of Blist printed cart											
14.	Batch detail printed carte	on										
15.	Seal the car											
	cello tape No. of carto	n in ono									<u> </u>	
16.	shipper											
17.	Batch detail											
18.	shipper labe Pasting of E											
		_										
Checl	ked by (Prod	uction)										
								At	tach addit	ional shee	t if requi	red
		P	repared By			Che	cked B	y		Approve	d By	
G •			v					-				
Sign	nature											
Date	e											



· / ·					- · · ·								
		B	АТСН І	PACKINO	G RECO	RD							
Prod	uct Code:				BPR N	No.:							
Prod	uct Name:				Gener	ric Nam	e: Acar	bose Tab	olets I	P 25 mg			
Effec	tive Date:]	Page No	.: 16 of	23	
Batcl	h No.:				Batch	Size:			;	Superse	rsedes No.: Nil		
5.2 In	-process checl	k by IPQA	for init	ial and eve	ry 60 min	l							
S.	In process	Date											
No.	checks	Time											
1.	Temp.												
2.	RH												
3.	Forming roll	er											
	temperature Sealing roller	r											
4.	Temperature												
	Check worki												
5.	NFD by remo												
	track												
6.	Tab. with for												
	black particle	9											
7.	Foil shifting Patab datail on foil												
8.	Batch detail on foil												
9.	No. of tab/ Blister Proper cutting of												
10.	Blister	gui											
11.	Leak test (Bi-hourly)												
12.	Proper gluing carton												
13.	No. of Blister printed cartor	n											
14.	Batch detail of printed carton	n											
15.	Seal the carto cello tape												
16.	No. of carton shipper	in one											
17.	Batch details shipper label												
18.	Pasting of B							_					
	ked by (IPQA)												
Check	xeu by (IPQA))											
		P	repare	d By		Che	cked B	y		A	pprove	d By	
Sign	ature							-				-	
Date	e												



			PRODUCTION DEPARTMENT										
		BAT	CH PACKI	ING	RECO	RD							
Prod	uct Code:				BPR N	0.:							
Prod	uct Name:				Generi	ic Nam	e: Acar	bose Tab	lets IF	25 mg			
Effec	ctive Date:								I	Page No	.: 17 of	23	
Batc	h No.:				Batch	Size:			S	Superse	des No.	: Nil	
			In-proce	ess c	heck by l	PQA fo	or initia	l and eve	ery 60	min			
S.	In process	Date											
No.	checks	Time											
1.	Temp.												
2.	RH												
3.	Forming ro												
	temperature Sealing roll												
4.	Temperatur	e											
	Check work	king of											
5.	NFD by rer one tablet f												
	track												
6.	Tab. with fo												
7.	black partic Foil shifting												
8.	Batch detai	-											
9.													
	Proper cutting of												
10.	Blister				_								
11.	Leak test (Bi-hourly)												
12.	Proper gluin carton												
13.	No. of Blist printed cart												
	Batch detai												
14.	printed cart	on											
15.	Seal the car	ton with											
	cello tape No. of carto	on in one											
16.	shipper												
17.	Batch detail shipper labe												
18.	Pasting of H												
Chec	ked by (IPQ												
L		I				<u> </u>	1			<u> </u>	1		1
		Pre	pared By			Che	cked B	y		A	pprove	d By	
Sign	nature												
Date	e												



		PRODUCTION DEPARTMENT									
		BAT	CH PACKING	RECO	RD						
Prod	luct Code:			BPR N	lo.:						
Prod	luct Name:			Gener	ic Name:	Acarbose 7	Tablets	s IP 25 mg			
Effec	ctive Date:			1					o.: 18 of	23	
Batc	h No.:								edes No.		
			In-process c	heck by l	PQA for	initial and	every				
S.	In process	Date									
No.	checks	Time									
1.	Temp.										
2.	RH										
3.	Forming rol	ller									
э.	temperature										
4.	Sealing roll										
	Temperatur Check work				+						
5.	NFD by ren one tablet fr track	noving									
6.	Tab. with fo	oreign /									
	black partic										
7.	Foil shifting										
8.											
9.											
10.	Proper cutti Blister	ng of									
11.	Leak test (Bi-hourly)										
12.	Proper gluir carton										
13.	No. of Blist printed carte										
14.	Batch detail printed carte	on									
15.	Seal the car	ton with									
16.	cello tape No. of carto	n in one									
10.	shipper										
17.	Batch detail shipper labe										
18.	Pasting of E										
Chec	ked by (IPQA										
L				1			Att	ach additio	onal shee	t if requi	red
		Prep	oared By		Chec	ked By		A	Approve	d By	
Sign	nature										
Date	e										



	BATCH	PACKING RECOR	RD		
Product Code:		BPR N	0.:		
Product Name		Generi	c Name: Acarbo	se Tablets IP 25 mg	
Effective Date	:				:: 19 of 23
Batch No.:		Batch	Size:	Superse	des No.: Nil
Weight limit	/EIGHING RECORE		Kg		
Shipper No.	Gross wt. In Kg.	Weighing done by		Gross wt. In Kg.	Weighing done by
1.			25.		
2.			26.		
3.			27.		
4.			28.		
5.			29.		
6.			30.		
7.			31.		
8.			32.		
9.			33.		
10.			34.		
11.			35.		
12.			36.		
13.			37.		
14.			38.		
15.			39.		
16.			40.		
17.			41.		
18.			42.		
19.			43.		
20.			44.		
21.			45.		
22.			46.		
22.			40.		
23.			48.		
	Voiabte			Waight:	
Min. Shipper V Chec	<u>Veight:</u> ked By (Production S	upervisor)	Max. Shipper	<u>Weight:</u> Verify By (IPQA	A)
	•	• /			·

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACK	ING RECORD	
Product Code:	BPR No.:	
Product Name:	Generic Name: Acarbose Tablet	ts IP 25 mg
Effective Date:		Page No.: 20 of 23
Batch No.:	Batch Size:	Supersedes No.: Nil

Loose Shipper No.:_____

7.0 RECONCILIATION OF PACKING MATERIAL:

S. No.	Material	Printed Aluminum foil	Base foil	Outer Cartons	Shippers
1.	Std. Qty.				
2.	Quantity Issued				
3.	Extra Qty. issued				
4.	Qty. used				
5.	Qty. returned (attach MRN)				
6.	Qty. destroyed after coding				
7.	Qty destroyed after pkg.				
8.	Total qty. destroyed				
9.	Qty. destroyed by				
10.	Checked by Prod. (Sign/Date)				
11.	Verified by IPQA (Sign/date)				
12.	Remarks				

8.0 FINISH PRODUCT SAMPLING AND QUALITY CONTROL APPROVAL:

Production person shall raise the sample request and provide to IPQA for sampling. IPQA shall perform sampling as per respective SOP and sent to QC.

Requisition raised By (Packing Supervisor): _____ Sampled By (IPQA): _____

Sampling Details:

S.No.	Sample detail	Quantity	Sampled By
1.	Sample for analysis		
2.	Control Samples		
3.	Stability Samples		
4.	Party Samples		
5.	Other samples		

	Prepared By	Checked By	Approved By
Signature			
Date			



	3		CITON DELAKING	• • •				
		BATCH PACKING	RECORD					
Product	Code:		BPR No.:					
Product	Name:		Generic Name	Acarbose Tablets	s IP 25 mg			
Effective	e Date:				Page No.: 21 of 23			
Batch N	[o.:		Batch Size:		Supersedes No.: Nil			
Trans Date Total No Unit per No. of B Qty of T Qty of sl Transfer	9.0 FINISHED GOODS TRANSFER TO FG STORES: Transfer finished goods to FG Stores. Through transfer ticket & attach a copy of T.T. to BPR Date:							
	-	_						
		pervisor CONCILIATION:						
S.No.		Particulars		In K	Ig In No.			
1.	Qty of	Tablets received by packing depart	rtment					
2.	Partial							
3.	Packing	g loss (Non recoverable)						
4.	Quanti	ty actually transferred to FG Store						
5.	Sample				· · · · ·			
5a.	Analys	is Sample Qty.						
5b.	Contro	l Samples Qty.						
5c.		y Sample Qty.						
5d.		ample Qty.						
6.		acked Quantity (4+5a+5b+5c+5d))					
7.	-	ntability=	,					
		-						
Reconciliation of Batch Yield:Yield= $\underline{\text{Total Quantity Packed (6) + Partial x 100}}_{\text{Batch size}}$ =								
-	Packing	Superviser)		(TP	PQA)			
(I aCKIIIg	Prepared By	Chec	ked By	Approved By			
Signatu	ure			J				
Date								



PM return note (if applicable) Specimens of Packing material In Process packing control reports TR of Finished Product Pack COA of Finished Product FG Goods Transfer Note Final Dispatch Note Destruction and approvals Deviation and its Justification

BA	ICH PACKING RI	ECORD			
Product Code: B		BPR No.:			
Product Name:	G	Generic Name: Acarbose Tablets IP 25 mg			
Effective Date:			Page No.: 22 of 23		
Batch No.: B		atch Size:	Supers	upersedes No.: Nil	
11.0 DEVIATION APPROVA Deviation No.	L: Reason for deviation	n			
12.0 REVIEW OF BPR:		Date:			
Particulars		Status		Checked By QA	
Signature of Authorized Persons					
Contents and Enclosures:			ľ		
PM Requisition					
PM Issue Order					
Excess material issue note, if an	y				

Reconcilia	ation and	Yields		
Legibility	of conten	its		
13.0 DISPATCH ADVICE:				
(FOR THE Product:			E USE OF QA ONLY) Batch N	0:
Q	ty. Releas	sed:	A.R. No:	
Released Date:				
The BPR has been reviewed and the above batch is released for DISPATCH.				
Si	Signature of QA Manager/Designee:		Date:	
		Prepared By	Checked By	Approved By
Signatu	re			
Date				



BATCH PACKING RECORD

Product Code:	BPR No.:		
Product Name:	Generic Name: Acarbo	Generic Name: Acarbose Tablets IP 25 mg	
Effective Date:		Page No.: 23 of 23	
Batch No.:	Batch Size:	Supersedes No.: Nil	

14.0 **HISTORY SHEET:**

BPR No.	New BPR No.	Revision No.	Reason of revision	Change Control No.
		00		

	Prepared By	Checked By	Approved By
Signature			
Date			