

			PRODUCITI	ON DEPARIME	N		
		BATC	CH PACKING I	RECORD			
Product Code	•			BPR N	No.:		
Product Name	e:			Gener	ic Name: A	torvastatin Calciu	m Tablets IP
Effective Date	2:				Page No.:	1 of 22	
Batch No.:			Batch Size:		Supersede	es No.:	
[							]
Location:							
Block: Product	ion Tablets	(PT)					
Label Claim:		Atorvastat eq. to Ato Excipients	coated tablet cont tin Calcium IP rvastatins  itanium Dioxide II	10 mg q.s.			
Mfg. Lic. No.:							
Product Lic. N	lo.:	NA					
Self-Life:		24 months	8				
Pack Style:		10x10 Tal	blets				
Country Name	e:	Domestic					
Mfg. Date:							
Exp. Date:							
BMR ISSUED	) No.:						
MRP:							
Party:							
			Issued By	y Stamp & Siş	gn.		
Responsibilit	y	Name	e	Designa	ation	Sign	Date
Prepared By							
Checked By							
Approved By	7						



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

Product Code:		BPR N	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 2 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### **1.0 GENERAL INSTRUCTIONS:**

- ➢ Good 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 N	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 3 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### 2. DISPENSING OF PACKING MATERIALS:

#### 2.1 Instructions:

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 dispensing 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	(IPQA):			
Sign & Date				

	Prepared By	Checked By	Approved By
Signature			
Date			

Date:



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR N	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			<b>Page No.:</b> 4 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### 2.4 BILL OF PACKING MATERIALS:

(BPR Copy)

Date: \_\_\_\_\_

Sr.	T.	Qty. for	@ Req.	Issued		Issued	Checke	ed By
No.	Items	1 Lac. In Kg/Nos.	Qty. In Kg/Nos.	Qty. In Kg/Nos.	A.R. No.	by Store	Prod.	QA
1	<b>Printed Foil</b> -0.025mm, Foil Width = 218 mm	4.0 Kg						
2	<b>Base Foil-0.14mm</b> Cold form Alu-Alu foil, Foil Width = 222 mm	16.0 Kg						
3	<b>CARTON -</b> Dim: 110 X 48 X 52 mm ( <b>10 x 10 Tabs.</b> )	1000 Nos.						
4	<b>5 PLY CORRUGATED</b> <b>BOX-</b> Dim (OD): 465 (L) x 435 (W) x 255(H) mm, ( <b>160 Cartons per box 4x8x5</b> ) Mkt. by address is printed in corr. box length panel in red colour.	07 Nos.						
5	<b>BOPP TAPE -</b> BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						

Note- @ Calculate the materials as per required batch size.

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



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR No	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 5 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### **BILL OF PACKING MATERIALS**

#### (STORE COPY)

Store copy page No.: 5 of 22

Date: \_\_\_\_\_

Sr. No.	<b>.</b>	Qty. for	@ Req.	Issued		Issued	Checke	ed By
	Items	1 Lac. In Kg/Nos.	Qty. In Kg/Nos.	Qty. In Kg/Nos.	A.R. No.	by Store	Prod.	QA
1	<b>Printed Foil</b> -0.025mm, Foil Width = 218 mm	4.0 Kg						
2	<b>Base Foil-0.14mm</b> Cold form Alu-Alu foil, Foil Width = 222 mm	16.0 Kg						
3	<b>CARTON -</b> Dim: 110 X 48 X 52 mm ( <b>10 x 10 Tabs.</b> )	1000 Nos.						
4	<b>5 PLY CORRUGATED</b> <b>BOX-</b> Dim (OD): 465 (L) x 435 (W) x 255(H) mm, ( <b>160 Cartons per box 4x8x5</b> ) Mkt. by address is printed in corr. box length panel in red colour.	07 Nos.						
5	<b>BOPP TAPE -</b> BOPP Pre Printed 48 mm x 65 mtrs.	01 Nos.						

Note- @ Calculate the materials as per required batch size.

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



### PHARMA DEVILS PRODUCTION DEPARTMENT

BATCH					
Product Code:		BPR N	0.:		
Product Name:			Generic Name: Atorvastatin Calcium Tablets IP		
Effective Date:			Page No.: 6 of 22		
Batch No.:	Batch Size:		Supersedes No.:		

#### **3.0 PACKING SPECIFICATION:**

S.		Over Printing Matter Standards		Checl	ced By	
No.	Description	(For Example only) Over Printing Matter Actual				
А.	Primary Packi	ng:				
1.	Alu-Alu					
	Alu-Alu Blister coding details	B. No MFG EXP M.R.P.Rs PER 10 TABS. INCL.OF ALL TAXES				
B.	Secondary Pac	king:	-	•	•	
	Unit Carton	Printed				
	Carton 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	160 cartons in one 5 ply shipper				
1.	Shipper coding details	 B.No MFG EXP Qty. 160 X 10 X 10 TABS.				
	Sealing of Shipper/BOPP Tape	Printed BOPP Tape in "H" type on top and	bottom.			

#### 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. ٠

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:	bde: BPR No.:		
Product Name:	oduct Name: Generic Name: Atorvastatin Calcium Tablets		
Effective Date:			Page No.: 7 of 22
Batch No.:	Batch Size:		Supersedes No.:

- Produce the alu-alu 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 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.

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

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

Sr.	Clearance Checks		Date							
No.	Cicui unce v	Cheeks	Time							
1.	1. Product name:									
2.	2. Area Cleanliness below/ Balance/ Pallets/ etc.									
3.	3. Machine Cleanliness									
	Prepared By		Chee	cked B	y	Ap	prove	l By		
Sign	Signature									
Date										

Date: \_\_\_\_\_



PRODUCTION DEPARTMENT

	BATC	H PACKING RE	CORD							
Product Code:			BPR No.:							
Produ	ict Name:			Generi	c Name: A	torvast	atin Ca	alcium '	Tablets	IP
Effect	tive Date:				Page No.	<b>:</b> 8 of 2	22			
Batch	1 No.:	Batch Size:			Supersec	les No.	:			
								1	1	
4.	Packaging material of previor remove.	us product								
5.	Over coding details on Bliste	rs								
Sr.	Clearance Checks	Date								
No.	Clearance Checks	Time								
6.	Over coding details on unit c	arton								
7.	Pasting cello tape									
8.	Over coding details on outer	carton								
9.	Product Packaging Insert									
10.	Specimen of 5 Ply Shipper co	oding								
11.	Correctness of status label									
12.	Daily Verification of balance	s								
Chec	ked by Production (Sign/Dat	e)								
Verif	ied 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 1 from QA		ereos given perator	No. of stereos returned by Operator		Total No. of stereos submitted to QA		Submitted by	Retrieved By (IPQA)
Carton	Blister	Carton	Blister	Carton	Blister	Carton	Blister	(Packing)	

#### **3.6 Line clearance overprinting of carton:**

- Line clearance of the area and machine. i.
- 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				
	Prepared By	Checked By	Approved By				
Signature							
Date							



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

	BPR No	0.:		
Product Name:		Generic Name: Atorvastatin Calcium Tablets IP		
		<b>Page No.:</b> 9 of 22		
Batch Size:		Supersedes No.:		

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

	Over print	ting details	DPatan		Shipper
S.No.	Details on PM (for example)	Actual details	– Blister (ALU-ALU)	Carton	
1.					
2.	Batch No.:				
3.	Mfg. Date:				
4.	Exp. Date:				
5.	M.R.P.: (Incl. of all taxes) Per 10 Tablets				
6.	Qty. 160x10x10 TABS.				
Dealdere	Signature				
Packing	Date				
ШОА	Signature				
IPQA	Date				

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

#### 3.7 Reconciliation of Packing Material:

Sr. No.	Particulars	Cartons	Shipper				
1	Quantity Issued						
2	Quantity coded						
3	Good inspected quantity						
4	Quantity rejected						
5	5 Qty. destroyed						
6 Qty. destroyed by							
Checked by Prod. (Sign/Date)							
Verified by	Verified by IPQA (Sign / Date)						

		Prepared By	Checked By	Approved By
Signa	ature			
Date				



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code: BPR No.:			0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 10 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### 3.8 Shipper coding:

- i. Arrange the klass marker of respective batch no. for coding on unit carton and arrange the alphabets for 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.

#### 4.0 ALU-ALU BLISTERING:

#### 4.1 Machine Setting:

1. Take line clearance from IPQA.

Line clearance certificate for area and equipments:							
Equipment	Alu-Alu Machine						
Equipment No.							
Equipment Cleaned By							
Batch No.							
	Equipment       Equipment No.       Equipment Cleaned By						

- 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 Temp150°C to 160°C.
- 8. Ensure proper Knurling and cutting length.
- 9. Check status label on Tablets containers.
- 10. Load the hopper with Tablets to be stripped.
- 11. Operate the Alu-Alu 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.

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR No.:		
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP	
Effective Date:			Page No.: 11 of 22	
Batch No.:	Batch Size:		Supersedes No.:	

- 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 Blister 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 Blister done by				
Counting of Blister done by				
Carton				
Insertion of Blister & Carton done by				
Inspection of over coding on carton done by				
Shipper coding done by				
Insertion of Carton in shipper done by				
Shipper sealed and weighed by				
Checked by		·		
Production/packing				
IPQA				

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR N	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 12 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### 5.0 IN PROCESS CHECK:

5.1 In-process check by production at initial and every 30 min.

Sr.	In process	Date							
No.	checks	Time							
1.	Temp.								
2.	RH								
3.	Forming rolle temperature	r							
4.	Sealing roller Temperature								
5.	Check workin NFD by remo one tablet from track	ving							
6.	Tab. with fore black particle								
7.	Foil shifting								
8.	Batch detail o								
9.	No. of tab/ Bl								
10.	Proper cutting Blister	g of							
11.	Leak test (Hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed carton								
14.	Batch detail o printed carton								
15.	Seal the cartor cello tape								
16.	No. of carton shipper								
17.	Batch details shipper label	on							
18.									
Check	xed by (Produc	ction)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

		D	AICH	ACN	und i	NECON	D							
Prod	uct Code:						BPR	R No.	:					
Product Name: Generic Na									<b>Name:</b> Atorvastatin Calcium Tablets IP					
Effective Date: Page No.: 13 of 22								f 22						
Batch No.: Batch Size:						:		1	Superse	des No	.:			
In-pro	-process check by production at initial and every 30 min.													
Sr.	In process	Date												
No.	checks	Time												
1.	Temp.													
2.	RH													
3.	Forming roller temperature	r												
4. Sealing roller Temperature														

1101		1 mie						
1.	Temp.							
2.	RH							
3.	Forming roller temperature							
4.	Sealing roller Temperature							
5.	Check working NFD by remov one tablet from track	ing 1 each						
6.	Tab. with forei black particle	gn /						
7.	Foil shifting							
8.	Batch detail on	foil						
9.	No. of tab/ Blis	ster						
10.	Proper cutting Blister	of						
11.	Leak test (Hourly)							
12.	Proper gluing of carton							
13.	No. of Blister i printed carton	n one						
14.	Batch detail on printed carton							
15.	Seal the carton cello tape							
16.	No. of carton in shipper							
17.	Batch details o shipper label	n						
18.	Pasting of BOI	PP tape						
Check	xed by (Product	ion)						

		Prepared By	Checked By	Approved By
Signatu	ure			
Date				



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

-			
Product Code:		BPR No.:	
Product Name:		Generic Nan	ne: Atorvastatin Calcium Tablets IP
Effective Date:		Pag	<b>e No.:</b> 14 of 22
Batch No.:	Batch Size:	Sup	ersedes No.:

#### In-process check by production at initial and every 30 min.

I.	seess encen sy	<b>L</b>	 		-				
Sr.	In process	Date							
No.	checks	Time							
1.	Temp.								
2.	RH								
3.	Forming roller temperature	r							
4.	Sealing roller Temperature								
5.	Check workin NFD by remo one tablet fror track	ving n each							
6.	Tab. with fore black particle	ign /							
7.	Foil shifting								
8.	Batch detail of	n foil							
9.	No. of tab/ Bl	ister							
10.	Proper cutting Blister	of							
11.	Leak test (Hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed carton								
14.	Batch detail of printed carton								
15.	Seal the carton cello tape								
16.	No. of carton shipper	in one							
17.	Batch details of shipper label	on							
18.	Pasting of BO	PP tape							
Check	xed by (Produc	tion)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR N	0.:
Product Name:		Generi	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 15 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### In-process check by production at initial and every 30 min.

Sr.	In process	Date						
No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature	r						
4.	Sealing roller Temperature							
5.	Check workin NFD by remo one tablet from track	ving n each						
6.	Tab. with fore black particle	eign /						
7.	Foil shifting							
8.	Batch detail o	n foil						
9.	No. of tab/ Bl	ister						
10.	Proper cutting Blister	g of						
11.	Leak test (Hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail o printed carton							
15.	Seal the cartor cello tape							
16.	No. of carton shipper							
17.	Batch details shipper label	on						
18.	Pasting of BO	PP tape						
Check	xed by (Produc	tion)						

Attach additional sheet if required....

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR N	D.:
Product Name:		Generie	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 16 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### 5.2 In-process check by IPQA for initial and every 60 min

Sr.	In process	Date						
No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature							
4.	Sealing roller Temperature							
5.	Check workir NFD by remo one tablet from track	oving						
6.	Tab. with fore black particle							
7.	Foil shifting							
8.	Batch detail of	on foil						
9.	No. of tab/ Bl	ister						
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail c printed carton							
15.	Seal the carto cello tape							
16.	No. of carton shipper							
17.	Batch details shipper label	on						
18.	Pasting of BC	OPP tape						
Checl	ked by (IPQA)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:	BP	PR No.:	
Product Name:	Ger	eneric Name: Atorvastatin Calcium Tablets I	Р
Effective Date:		Page No.: 17 of 22	
Batch No.:	Batch Size:	Supersedes No.:	

#### In-process check by IPQA for initial and every 60 min

Sr.	In process	Date						
No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature							
4.	Sealing roller Temperature							
5.	Check workin NFD by remo one tablet from track	oving						
6.	Tab. with fore black particle							
7.	Foil shifting							
8.	Batch detail o	on foil						
9.	No. of tab/ Bl	ister						
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton	ı						
14.	Batch detail o printed carton	ı						
15.	Seal the carto cello tape							
16.	No. of carton shipper							
17.	Batch details shipper label	on						
18.	Pasting of BC	OPP tape						
Check	ked by (IPQA)							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:		BPR No	<b>D.:</b>
Product Name:		Generie	e Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 18 of 22
Batch No.:	Batch Size:		Supersedes No.:

#### In-process check by IPQA for initial and every 60 min

Sr.	In process	Date						
No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming rolle temperature							
4.	Sealing roller Temperature							
5.	Check workin NFD by remo one tablet from track	oving						
6.	Tab. with fore black particle							
7.	Foil shifting							
8.	Batch detail o	on foil						
9.	No. of tab/ Bl	ister						
10.	Proper cutting Blister	g of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail o printed carton	1						
15.	Seal the carto cello tape							
16.	No. of carton shipper							
17.	Batch details shipper label	on			 			
18.	Pasting of BC	PP tape						
Checl	ked by (IPQA)							

Attach additional sheet if required....

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code: BPR No.:			).:
Product Name:	G	eneric	e Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 19 of 22
Batch No.:	Batch Size:		Supersedes No.:

### **6.0 SHIPPER WEIGHING RECORD:** Weight limit for filled shipper:

1.   2.   3.   4.   5.					
3. 4.			27.		
4.			28.		
			29.		
5.			30.		
			31.		
6.			32.		
7.			33.		
8.			34.		
9.			35.		
10.			36.		
11.			37.		
12.			38.		
13.			39.		
14.			40.		
15.			41.		
16.			42.		
17.			43.		
18.			44.		
19.			45.		
20.			46.		
21.			47		
22.			48.		
23.					
24.					
25.					
26.					
Min. Shipper V	Veight:		Max. Shipper	Weight: Verify By (IPQ)	<u> </u>
Cnec	ked By (Production S	ирегизог)		verny by (IPQ)	<b>A</b> )
	Prepare	d By	Checked By	A	pproved By
Signature					



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

Product Code:	]	BPR No	D.:
Product Name:		Generic	c Name: Atorvastatin Calcium Tablets IP
Effective Date:			Page No.: 20 of 22
Batch No.:	Batch Size:		Supersedes No.:

Shipper No.	Gross wt. In Kg.	Weighing done by	Shipper No.	Gross wt. In Kg.	Weighing done by

### Loose Shipper No.:\_\_\_\_\_

#### 7.0 RECONCILIATION OF PACKING MATERIAL:

Sr. No.	Material	Printed Aluminum foil	Base foil	Printed Cartons	BOPP Tape	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					
Check	xed by Prod. (Sign/Date)					
Verifi	ed by IPQA (Sign/Date)					
10.	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 sample		

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

			FRODUCTON	PUMANINEN		
		BATCH	PACKING RECO	RD		7
Product Code: BPR No.:						
	uct Name:	:			c Name: Atorvastatir	n Calcium Tablets IP
Effec	tive Date:				Page No.: 21 of 22	
Batch			Batch Size:		Supersedes No.:	
Tr Da Total Unit J No. o Qty o	ansfer finis ate: No. of ship per shipper f Blister pe f Tablets tr	opers packed or Carton ransferred to BSR		cket & attach	a copy of T.T. to BPR	
		ransferred to BSR				
	sfer note No					
		Supervisor				
U	of BSR Su	pervisor CONCILIATION:				
<b>S</b> .	ALCH KE		1-		<b>T T</b> 7	T bi
No.			articulars		In Kgs.	In Nos.
1.	-	blets received by pack	ing department			
2.	Partial					
3.	-	Packing loss (Non recoverable)				
4.	Quantity actually transferred to FG Store					
5.	Sample					
5a.	-	Sample Qty.				
5b.		amples Qty.				
5c.		Sample Qty.				
5d.	Party Sam		1			
6.	Total packed Quantity (4+5a+5b+5c+5d)					
7.	Accounta	bility=				
Remai	Yield	Batch :	<u>acked (6) + Partial x</u> 1 size x 100 % (NLT 97.0 %)			
	(Packing	g Superviser)			(IPQA)	
		Prepare	d By	Checked	By	Approved By
Sign	ature					
Date						



	PHARMA DEVILS PRODUCTION DEPARTMENT				
	BATC	H PACKING REC	CORD		
Product Code:	Product Code: BPR No.:				
Product Name:			Gener	ic Name: Atorvastat	in Calcium Tablets IP
Effective Date:				Page No.: 22 of 2	2
Batch No.:		Batch Size:	Supersedes No.:		
11.0 DEVIATION	NAPPROVAL:				
Deviation	No.		Reaso	n for deviation	
12.0 REVIEW OI	F BPR:			Date:	
Particulars			S	tatus	Checked By QA
Signature of Autho	orized Persons				
Contents and End					
PM Requisition					
PM Issue Order					
Excess material iss	ue note, if any				
PM return note (if	applicable)				
Specimens of Pack	ing material				
In Process packing	control reports				
TR of Finished Pro	oduct Pack				
COA of Finished H	roduct				
FG Goods Transfe	r Note				
Final Dispatch Not	e				
Destruction and ap	provals				
Deviation and its Justification					
Reconciliation and	Yields				
13.0 DISPATCH A	ADVICE:	(EOD THE I	JSE OF QA ON	NI V)	
Product:			JU OF VAU	Batch No:	
	Qty. Released: A.R. No:				
- •	Date:				
		and the above batcl	h is released for	DISPATCH.	
-	of QA Manager/I	Designee:		Date:	
14.0 HISTORY SH			<u> </u>		
BPR No.		New BPR No.	Revision	Reason	of revision
	1		1 1		

	Prepared By	Checked By	Approved By
Signature			
Date			