

	BATCH PA	ACKING F	RECORD			
Product Code:			BPR No.:		,	
Product Name:	<u>_</u>					
Effective Date:	Page No.: 1 of					
Batch No.:		Batch Siz	ze:	Su	persedes No.: Nil	
		ALU-AL	LU PACKING			
Location:						
Block: Production Tablets	(PT)					
	Each uncoated ta	ablet contain	s:			
Label Claim:	Betahistine Dihydrochloride IP 8 mg					
	Excipients		q.s.			
Mfg. Lic. No.:						
Product Lic. No.:	NA					
Self-Life:	24 months					
Pack Style:	10 x 10 Tablets					
Country Name:	Domestic					
Mfg. Date:						
Exp. Date:						
BMR Issued No.:						
MRP:						
Party:						

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

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

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 No.:		
Product Name:		Generic Name: Betahistine Tablets IP		
Effective Date:			Page No.: 3 of 23	
Batch No.:	Batch Size:	}	Supersedes No.: Nil	

2.0 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:

Sign & Date

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 Supervisor): Sign & Date				
Line clearance Given By	(IPQA):			

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:		
Product Name:		Generic Name: Betahistine Tablets IP		
Effective Date:			Page No.: 4 of 23	
Batch No.:	Batch Size:		Supersedes No.: Nil	

2.4 BILL OF PACKING MATERIALS:

(BPR Copy) Date: _____

Sr.	T4	Std. Qty.	#Req.	Issued	A D N	Issued	Checked By	
No.	Items	for 1 Lac. In Kg/Nos.	Qty. In Kg/Nos.		A.R. No.	by Store	Prod.	QA
1	Printed Aluminium Foil- 0.025mm, Foil Width = 218 mm	4.00 Kg						
2	Base Foil- 0.14mm, Cold form Alu-Alu foil, Foil Width = 222 mm	16.00 Kg						
3	Carton - Dim: 110 X 48 X 52 mm (10 x 10 Tabs.)	1000 Nos.						
4	5 PLY CORRUGATED BOX- Dim (OD): 465 (L) x 435 (W) x 255(H) mm, (160 Cartons per box 4x8x5) Plain Corr. box	07 Nos.						
5	BOPP TAPE - BOPP Plain 48 mm x 65 mtrs.	01 Nos.						

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

Dispensed By: Verified By:

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	1
Product Name:		Generic Name: Betahist	ine Tablets IP
Effective Date:			Page No.: 5 of 23
Batch No.:	Batch Size:		Supersedes No.: Nil

(Store) (Prod. Supervisor) (QA)
Store copy page No.: 5 of 22

BILL OF PACKING MATERIALS

(STORE COPY) Date: _____

S.	Thomas	Std. Qty.	#Req.	Issued	A D No	Issued	Check	ed By
No ·	Items	for 1 Lac. In Kg/Nos.	Qty. In Kg/Nos.	Qty. In Kg/Nos.	A.R. No.	by Store	Prod.	QA
1	Printed Aluminium Foil- 0.025mm, Foil Width = 218 mm	4.00 Kg						
2	Base Foil- 0.14mm, Cold form Alu-Alu foil, Foil Width = 222 mm	16.00 Kg						
3	Carton - Dim: 110 X 48 X 52 mm (10 x 10 Tabs.)	1000 Nos.						
4	5 PLY CORRUGATED BOX- Dim (OD): 465 (L) x 435 (W) x 255(H) mm, (160 Cartons per box 4x8x5) Plain Corr. box	07 Nos.						
5	BOPP TAPE - BOPP Plain 48 mm x 65 mtrs.	01 Nos.						

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

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

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

Dispensed By: Checked By: Verified By: (Store) (Prod. Supervisor) (QA)

3.0 PACKING SPECIFICATION:

	7				
Sr.	Description	Over Printing Matter Standards	Over Printing Matter Actual		ked By
No.	•	(For Example only)	8	Prod.	QA
A.	Primary Packin	ng:			
1.	ALU-ALU Blis	ster:			
	Alu-Alu Blister coding details	B. No. MFG. EXP. M.R.P.Rs PER 10 TABS. INCL.OF ALL TAXES			
В.	Secondary Pac	Secondary Packing:			
	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 Packin	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 10X10 TABS.			
	Sealing of Shipper/BOPP Tape	Plain BOPP Tape in "H" type on top and bot	tom.		

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahist	tine Tablets IP
Effective Date:			Page No.: 7 of 23
Batch No.:	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 218 mm printed aluminum foil & 222 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.
- 160 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 Plain 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 - Date: _____

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			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahistine Tablets IP	
Effective Date:			Page No.: 8 of 23
Batch No.:	Batch Size:		Supersedes No.: Nil

2 2	T . 1		/T '4' 1/ 1 '6'		`
	Line clearance	cneck	(Initial/shift	cnange	overn

	Line Clearance of Packing Line	Please Tick √ If Yes & X If No or Not Applicable
--	--------------------------------	--

Sr.	Clearance Checks	Date					
No.	Cital and Citeks	Time					
1.	Product name:						
2.	Area Cleanliness below/ Balance/ etc.	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						
Checl	ked by Production (Sign/Date)						
Verifi	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;

No. of stereos received from QA	No. of stereos given to operator	No. of stereos returned by operator	Total No. of stereos submitted to QA	Submitted by (Packing)	Retrieved By (IPQA)
------------------------------------	----------------------------------	---	--------------------------------------	------------------------------	------------------------

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahist	ine Tablets IP
Effective Date:			Page No.: 9 of 23
Batch No.:	Batch Size:		Supersedes No.: Nil

Carton	Blister	Carton	Blister	Carton	Blister	Carton	Blister	

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

	Over printing details		Distan		
Sr. No.	Details on PM (for example)	Actual details	Blister (ALU-ALU)	Outer Carton	Shipper
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.				
Packing	Signature				
Packing	Date				
IDOA	Signature				
IPQA	Date				

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahist	tine Tablets IP
Effective Date:			Page No.: 10 of 23
Batch No.:	Batch Size:		Supersedes No.: Nil

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

3.7 Reconciliation of Packing Material:

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

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:

4.1 Machine Setting:

1. Take line clearance from IPQA.

quipment ALU-A	ALU Machine
uinment No	
Juipinent No.	
quipment Cleaned By	
atch No.	
ון	uipment 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.

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahist	tine Tablets IP
Effective Date:			Page No.: 11 of 23
Batch No.:	Batch Size:	}	Supersedes No.: Nil

- 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 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 Blister done by				
Counting of Blister done by				
Carton printing checked by				
Insertion of Blister & Carton				
done by				

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:						
Product Name:		Generic Name: Betahistine Tablets IP						
Effective Date:			Page	No.: 12 of 23				
Batch No.:	Batch Size:		Supe	rsedes No.: Nil				
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

IPQA

Production/packing

5.0 IN PROCESS CHECK:5.1 In-process check by production at initial and every 30 min.

	process cheen	<i>.</i> 1			-				
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	ving n each							
6.	Tab. with fore black particle								
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	n with							

	Prepared By	Checked By	Approved By
Signature			
Date			



		В	SATCH	PAC	KING	RECO	RD							
Proc	luct Code:						BPR	R No.:			1			
Proc	luct Name:						Gen	eric Na	ame: Be	tahisti	ine Tabl	lets IP		
Effe	ctive Date:										Page N	lo.: 13	of 23	
	h No.:				Ba	tch Size	e:				Supers			
16.	No. of carton shipper	in one												
17.	Batch details shipper label	on												
18.	Pasting of BC	PP tape												
Chec	ked by (Produc	·												
			n-proces	ss chec	ek by pi	roductio	n at ini	tial and	l every 3	0 min.	·			
Sr.	In process	Date												
No.	checks	Time												
1.	Temp.													
2.	RH													
3.	Forming rolle temperature	er												
4.	Sealing roller Temperature													
5.	Check working of NFD by removing one tablet from each													
6.	track Tab. with fore black particle													
7.	Foil shifting													
8.	Batch detail of	n foil												
9.	No. of tab/ Bl	ister												
10.	Proper cutting Blister													
11.	Leak test (Hourly)													
12.	Proper gluing carton	of												
13.	No. of Blister printed cartor													
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	on												
18.	Pasting of BC	PP tape												
		F	repare	d Bv			Che	cked B	v		Aı	prove	d Bv	
Sign	nature			<u> </u>					J			p2-0-10	 J	
Dat														



PRODUCTION DEPARTMENT

BA	TCH PACI	KING	RECOF	RD								
Product Code:				BPR No.:								
Product Name:		Gen	eric Na	me: B	etahisti	ine Tabl	ets IP					
Effective Date:						Page N	[o.: 14	of 23				
Batch No.:	tch Size	:				Supers	edes N	o.: Nil				
Checked by (Production)												

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								
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								
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 carton with cello tape		_						
16.	No. of carton in one shipper					 			
17.	Batch details shipper label	on							

	Prepared By	Checked By	Approved By
Signature			
Date			



Pharm	na Devila			,		. , , ,								
		BA	TCH PAG	CKING	RECO	RD								
Prod	luct Code:					BPR	No.:							
	luct Name:					_		ame: Be	etahist	ine Tab	Tablets IP			
Effec	ctive Date:					II.				Page N	No.: 15	of 23		
Batc	h No.:			Ba	tch Siz	e:					sedes N			
18.	Pasting of BC	OPP tape												
Checl	ked by (Produ	ction)												
			process ch	eck by pi	oductio	n at ini	tial and	l every 3	30 min	ı .	1	T		
Sr. No.	In process checks	Date												
1.	Temp.	Time												
2.	RH													
	Forming rolle													
3.	temperature													
4.	Temperature	Sealing roller												
5.	Check working NFD by remoderable from the contraction of the contracti	oving												
	track													
6.	Tab. with for black particle													
7.	Foil shifting													
8.	Batch detail of	on foil												
9.	No. of tab/ Bl													
10.	Proper cutting Blister	g of												
11.	Leak test (Hourly)													
12.	Proper gluing carton	g of												
13.	No. of Blister printed cartor													
14.	Batch detail of printed cartor	on												
15.	Seal the carton with cello tape													
16.	No. of carton shipper	in one												
17.	Batch details	on												
			pared By	,		Cho	cked B	V		Α.	pprove	d Rv		
		110	partu by			CHe	cacu D	J		A	pprove	и Бу		
Sign	nature													
Date	e													



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

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Prod	luct Code:					BPR No	.:							
Proc	luct Name:					Generic Name: Betahistine Tablets IP								
Effe	ctive Date:								Page	No.: 16	of 23			
Batc	h No.:			Batch S	Size:				Super	rsedes l	No.: Nil			
	shipper label													
18.	Pasting of BOPP tape													
Chec	ked by (Production)													
				•	<u> </u>			Attacl	n additio	onal she	et if requ	ired		

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	r						
4.	Sealing roller Temperature							
5.	Check workin NFD by remo one tablet from track	wing m each						
6.	Tab. with fore black particle							
7.	Foil shifting							
8.	Batch detail o	n 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	ı						
15.	Seal the carto							
16.	No. of carton shipper	in one				_		

	Prepared By	Checked By	Approved By
Signature			
Date			_



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

	, L	711 (1)	111101	XII 1 (KECO.								
Prod	uct Code:					BPI	R No.:						
Prod	uct Name:					Ger	eric Na	ame: B	etahisti	ne Tabl	lets IP		
Effec	ctive Date:									Page N	[o.: 17	of 23	
Batc	h No.:			В	atch Size	:				Supers	edes N	o.: Nil	
17.	Batch details on shipper label												
18.	Pasting of BOPP tape												
Checked by (IPQA)													

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

			1		Q I		 -		
Sr. No.	In process checks	Date Time							
1.	Temp.	I.							
2.	RH								
3.	Forming rolle temperature								
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								
10.	Proper cutting Blister	g of							
11.	Leak test (Bi-hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed carton	Į.							
14.	Batch detail o printed carton	L							
15.	Seal the cartor cello tape								
16.	No. of carton shipper	in one							

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

		 	111	TLE CO.								
Prod	luct Code:				BPI	R No.:						
Prod	luct Name:				Generic Name: Betahistine Tablets IP							
Effe	ctive Date:						Page N	o.: 18	of 23			
Batc	h No.:		В	atch Size	:				Supers	edes N	o.: Nil	
17.	Batch details on shipper label											
18.	Pasting of BOPP tape											
Checl	ked by (IPQA)											

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

	in process electroly in Q12 101 minute and every 60 min.												
Sr. No.	In process checks	Date Time											
1.	Temp.	ı											
2.	RH												
3.	Forming rolle temperature												
4.	Sealing roller Temperature												
5.	Check working NFD by remoone tablet from track	oving m each											
6.	Tab. with fore black particle	eign /											
7.	Foil shifting												
8.	Batch detail o	n foil											
9.	No. of tab/ Bl												
10.	Proper cutting Blister	g of											
11.	Leak test (Bi-hourly)												
12.	Proper gluing carton												
13.	No. of Blister printed carton	l											
14.	Batch detail of printed carton	l											
15.	Seal the carto cello tape												
16.	No. of carton shipper	in one											

	Prepared By	Checked By	Approved By
Signature			
Date			



17.

18.

19.

20.

PHARMA DEVILS

PRODUCTION DEPARTMENT

Pharma Devila											
	BATCH PACKING RECORD Product Code: RPP No -										
Product Co	ode:			BPR No.:		L.					
Product Na	ime:			Generic Nar	ne: Betahisti	ine Tab	lets IP				
Effective D	ate:					Page N	lo.: 19	of 23			
Batch No.:			Batch Size	:		Supers	sedes N	o.: Nil			
					1			1	1		
	details on er label										
	g of BOPP tape								1		
Checked by											
									1		
	R WEIGHING RECO		_ Kg to	Kg	Attach	addition	nal sheet	: 1f requi	ired		
Shipper No	o. Gross wt. In Kg	g. Weigh	ning done by	Shipper No.	Gross wt.	In Kg.	Weigh	ning do	ne by		
1.		, 3	<u> </u>	26.							
2.				27.							
3.				28.							
4.				29.							
5.				30.							
6.				31.							
7.				32.							
8.				33.							
9.				34.							
10.				35.							
11.				36.							
12.				37.							
13.				38.							
14.				39.							
15.				40.							
16.			41.								

	Prepared By	Checked By	Approved By
Signature			
Date			_

42.

43. 44.

45.



Pharm												
	BATO	CH PACKING RECO	RD									
Prod	luct Code:		BPR No.:									
Prod	luct Name:		Generic Nar	ne: Betahist	ine Tab	lets IP						
Effec	ctive Date:				Page N	No.: 20 of 23						
Batc	h No.:	Batch Siz	e:		Supers	sedes No.: Nil						
						,						
Ship	oper No. Gross wt. In Kg	. Weighing done by	Shipper No.	Gross wt.	In Kg.	Weighing done by						
2	1.		46.									
2	22.		47									
2	3.		48.									
2	4.											
2:	5.											
	. Shipper Weight:		Max. Shipper	Weight:								
	Checked By (Production	n Supervisor)		Verify B	y (IPQA	A)						
												
Loose	Shipper No.:											
7.0 RI	ECONCILIATION OF PACI	KING MATERIAL:										
Sr. No.	Material	Printed Aluminum foil	Base foil	Outer C	artons	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											
	ked by Prod. (Sign/Date)											
	ed by IPQA (Sign/Date)											
10.	Remarks											
8.0 F	INISH PRODUCT SAMPLI	NG AND QUALITY CO	ONTROL APPR	OVAL:								
	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.											
Re	equisition raised By (Packing	Supervisor):	Sampled By	(IPQA):								
Sa	ampling Details:											

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

BATCH PACKING RECORD

Product Code:		BPR No.:	
Product Name:		Generic Name: Betahistine Tablets IP	
Effective Date:			Page No.: 21 of 23
Batch No.:	Batch Size:		Supersedes No.: Nil

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

9.0 FINISHED GOODS TRANSFER TO FG STORES:

Transfer	finished g	goods to	FG Stores.	Through	transfer	ticket &	& attach	a copy o	f T.T. t	o BPR
Date:										

Total No. of shippers packed	
Unit per shipper	
No. of Blister per Carton	
Qty of Tablets transferred to BSR	
Qty of shippers transferred to BSR	
Transfer note No.	
Sign of Packing Supervisor	
Sign of BSR Supervisor	

10.0 BATCH RECONCILIATION:

Sr. No.	Particulars	In Kgs	In Nos.
1.	Qty of Tablets received by packing department		
2.	Partial		
3.	Packing loss (Non recoverable)		
4.	Quantity actually transferred to FG Store		
5.	Sample		
5a.	Analysis Sample Qty.		
5b.	Control Samples Qty.		
5c.	Stability Sample Qty.		
5d.	Party Sample Qty.		
6.	Total packed Quantity (4+5a+5b+5c+5d)		

	Prepared By	Checked By	Approved By
Signature			
Date			



E V	ATCH PACKING REC	CODD			
	TCH FACKING REC				
Product Code:		BPR No.: Generic Name: Betahistine Tablets IP			
Product Name:		_			
Effective Date:	Dotals 6	N	Page No.: 22 of 23		
Batch No.:	Batch S	Size:	Supersedes No.: Nil		
7. Accountability=					
Reconciliation of Batcl	h Yield:	-	1		
Yield = Total Quar	ntity Packed (6) + Partial x Batch size	x 100			
=	x 100)			
=	% (NLT 97.0 %)				
Remark:					
(Packing Superviser)	_		(IPQA)		
11.0 DEVIATION APPROVA					
Deviation No.	Reason for deviation				
10.0 REVIEW OF BPR:		Date:			
Particular	s	Status	Checked By QA		
Signature of Authorized Persons	3		, ,		
Contents and Enclosures:	I				
PM Requisition					
PM Issue Order					
Excess material issue note, if an	v				
PM return note (if applicable)					
Specimens of Packing material					
In Process packing control repor	rts				
TR of Finished Product Pack					
COA of Finished Product					
FG Goods Transfer Note					
Final Dispatch Note					
Destruction and approvals					
Deviation and its Justification					
Reconciliation and Yields					
Legibility of contents					
13.0 DISPATCH ADVICE:					
Pr	epared By	Checked By	Approved By		

	Prepared By	Checked By	Approved By
Signature			
Date			



Product Code: Product Name: Effective Date:	BATCH PACKI	NG RECORD	
Product Name:			
		BPR No.:	'
Effective Date:		Generic Nar	me: Betahistine Tablets IP
		·	Page No.: 23 of 23
Batch No.:		Batch Size:	Supersedes No.: Nil
Released Date	:		A.R. No:
	een reviewed and the above A Manager/Designee:	batch is released for DISPAT Date:	
4.0 HISTORY SH	EET:		
BPR No.	New BPR	No. Revision	n No. Reason of revision

	Prepared By	Checked By	Approved By
Signature			
Date			