

PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:	
Product Name:	Generic Name: Telmisart	an Tablets IP 80 mg
Effective Date:		<b>Page No.:</b> 1 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

Location:	
<b>Block:</b> Production Tablets	(PT)
Label Claim:	Each film coated tablet contains: Telmisartan IP
Mfg. Lic. No.:	
Product Lic. No.:	NA 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

<b>Product Code:</b>	BPR No.:	
Product Name:	Generic Name: 7	Telmisartan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 2 of 24
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

<b>Product Code:</b>	BPR No.:	
Product Name:	Generic Name: Telmisa	artan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 3 of 24
Ratch No.:	Batch Size:	Supersedes No.: Nil

#### 2.0 DISPENSING OF PACKING MATERIALS:

Date:		

#### 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:

Sr. 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.:	

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

	T			
Product Code:	BPR No.:	BPR No.:		
Product Name:	Generic Name	: Telmisartan Tablets IP 80 mg		
<b>Effective Date:</b>		<b>Page No.:</b> 4 of 24		
Batch No.:	<b>Batch Size:</b>	Supersedes No.: Nil		
Checked By (Packing Supervisor):				
Sign & Date				
Line clearance Given By(IPQA):				
Sign & Date				

#### **2.4 BILL OF PACKING MATERIALS:**

(BPR Copy) Date: \_\_\_\_\_

Sr.	Items	Std. Qty. for 1 Lac.	#Req. Qty.	Issued Qty. In	A.R. No.	Issued by Store	Checked By	
No.		In Kg/Nos	In Kg/Nos.	Kg/Nos.	11111111111		Prod.	QA
	Printed Aluminium Foil-							
1	0.025mm,	4.00 Kg						
	Foil Width = 212 mm							
	Base Foil- 0.14mm,							
2	Cold form Alu-Alu foil,	20.00 Kg						
	Foil Width = 212 mm							
3	Outer Carton – Dim: 105 X	1000 Nos.						
3	44 X 46 mm ( <b>10 x 10 Tabs.</b> )	1000 1103.						
	5 PLY CORRUGATED							
	<b>BOX-</b> Dim (OD): 465 (L) x							
4	435 (W) x 255(H) mm,	05 Nos.						
	(200 Cartons per box 5x8x5)							
	Mkt.by address is printed in corr. box length panel in red colour.							
5	BOPP TAPE - BOPP Pre	01 Nos.						
-	Printed 48 mm x 65 mtrs.							

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

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

<b>Product Code:</b>	BPR No.:		
Product Name:	Generic Name: 7	Generic Name: Telmisartan Tablets IP 80 mg	
Effective Date:		<b>Page No.:</b> 5 of 24	
Batch No.:	Batch Size:	Supersedes No.: Nil	

Dispensed By: (Store)

Checked By: (Prod. Supervisor)

Verified By: (QA)

Store copy page No.: 5 of 22

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

(STORE COPY) Date: \_\_\_\_\_

Sr.	Items	Std. Qty. for 1 Lac.	#Req. Qty.	Issued Qty. In	A.R. No.	Issued by	Checked By	
No.	20022	In Kg/Nos.	In Kg/Nos.	Kg/Nos.	12/24/1/00	Store	Prod.	QA
1	Printed Aluminium Foil- 0.025mm, Foil Width = 212 mm	4.00 Kg						
2	<b>Base Foil-</b> 0.14mm, Cold form Alu-Alu foil, Foil Width = 212 mm	20.00 Kg						
3	Outer Carton – Dim: 105 X 44 X 46 mm (10 x 10 Tabs.)	1000 Nos.						
4	<b>5 PLY CORRUGATED BOX-</b> Dim (OD): 465 (L) x 435 (W) x 255(H) mm, (200 Cartons per box 5x8x5) Mkt.by address is printed in corr. box length panel in red colour.	05 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.

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

<b>Product Code:</b>	BPR No.:	BPR No.:		
Product Name:	Generic Name:	Generic Name: Telmisartan Tablets IP 80 mg		
<b>Effective Date:</b>		<b>Page No.:</b> 6 of 24		
Batch No.:	Batch Size:	Supersedes No.: Nil		

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

### 3.0 PACKING SPECIFICATION:

Sr.	Description	Over Printing Matter Standards	Over Printing Matter Actual	Checked By	
No.	Description	- (For Example only)		Prod.	QA
A.	Primary Packin	ng:			
1.	ALU-ALU Blis	ter:			
	Alu-Alu Blister coding details	B. No. MFG. EXP. M.R.P.Rs PER 10 TABS. INCL.OF ALL TAXES			
В.	Secondary Paci	king:			
	Carton	Printed	Carton details: 10 x 10 Tablets		
1.	Carton coding details	Batch No.: Mfg. Date: Exp. Date: MRP Rs.: (Incl. of all Taxes) Per 10 Tablets			
C.	Tertiary Packing				
1.	5 ply shipper 5 ply printed shipper				

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:			
Product Name:	Generic Name: Telmisa	Generic Name: Telmisartan Tablets IP 80 mg		
<b>Effective Date:</b>		<b>Page No.:</b> 7 of 24		
Batch No.:	Batch Size:	Supersedes No.: Nil		

Shipper details	200 cartons in one 5 ply shipper		
Shipper coding details	B.No. MFG. EXP. Qty. 200 X 10X10 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.
- 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 - Date: \_\_\_\_\_

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:	BPR No.:	
Product Name:	Generic Name: Te	elmisartan Tablets IP 80 mg	
<b>Effective Date:</b>		<b>Page No.:</b> 8 of 24	
Batch No.:	Batch Size:	Supersedes No.: Nil	

#### **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.

#### 3.3

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

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

Sr.	Classes Charles	Date					
No.	Clearance Checks						
1.	Product name:						
2.	Area Cleanliness below/ Balance/ etc.	Pallets/					
3.	Machine Cleanliness						
4.	Packaging material of previous product remove.						
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						

	Prepared By	Checked By	Approved By
Signature			
Date			_



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

			1							
<b>Product Code:</b>			BPR N	BPR No.:						
Product Name: Generic Nar			ic Nam	e: Telmi	: Telmisartan Tablets IP 80 mg					
Effective Date:					Pa	age No.	: 9 of 2	4		
Batch	No.:	Batc	h Size:			Sı	ipersec	des No.: Nil		
11.	Correctness of status label									
12.	Daily Verification of balances									
Checked by Production (Sign/Date)										
Verified by IPQA (Sign/Date)										

#### 3.5 Verification of tablet received from core area:

	<b>Total Container No.</b>	Total Weight	<b>Checked by Production</b>	Verified by IPQA
ì				

#### 3.6 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				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.
- 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						

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

<b>Product Code:</b>	BPR No.:			
Product Name:	Generic Name: Telmisartan Tablets IP 80 mg			
Effective Date:		<b>Page No.:</b> 10 of 24		
Ratch No.:	Ratch Size:	Supersedes No.: Nil		

### Over coding detail for blister, carton and shipper

	Over print	Distan			
Sr. No.	Details on PM (for example)	Actual details	Blister (ALU-ALU)	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. 200 x 10 x 10 TABS.				
Packing	Signature				
Packing	Date				
IDO A	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	Outer Cartons	Shipper
1	Quantity Issued		
2	Quantity coded		
3	Good inspected quantity		
4	Quantity rejected		
5	Qty. destroyed		
6	Qty. destroyed by		
Checked by Prod. (Sign/Date)			
Verifi	ed by IPQA (Sign / Date)		

#### 3.8 Shipper coding:

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### BATCH PACKING RECORD

Product Code:	BPR No.:	<u> </u>
Product Name:	Generic Name: Telmisar	rtan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 11 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

- 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.

Line clearance	ce certificate for area and equ	ipments:
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(IPQA): Sign & Date		

- 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 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.

	Prepared By	Checked By	Approved By
Signature			
Date			



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#### BATCH PACKING RECORD

Product Code:	BPR No.:	·
Product Name:	Generic Name: Telm	nisartan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 12 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

#### 4.3 Alu-Alu 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 printing checked by				
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				

#### **5.0 IN PROCESS CHECK:**

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

Sr.	In process	Date						
No.	In process checks	Time						
1.	Temp.							
2.	RH							
2	Forming roller temperature	r						
3.	temperature							

	Prepared By	Checked By	Approved By
Signature			
Date			



		В	ATCH	PACE	ANG I	RECO								
	uct Code:					BPR No.:								
	uct Name:						Generi	ic Nam	e: Telm					
	ctive Date:											<b>No.:</b> 13 of 24		
Batc	h No.:				F	Batch S	ize:			S	Supersedes No.: Nil			
	T ==		1										1	1
4.	Sealing roller Temperature													
	Check worki													
5.	NFD by remo	oving												
J.	one tablet fro	m each												
	Tab. with for	eign /												
6.	black particle													
7.	Foil shifting													
8.	Batch detail	on foil												
9.	No. of tab/ B													
10.	Proper cuttin	g of												
	Blister Leak test													
11.	(Hourly)													
12.	Proper gluing	g of												
12.	carton													
13.	No. of Bliste printed carto													
14.	Ratch datail													
14.	printed carto				<u> </u>									
15.	Seal the carto	on with												
1,0	No. of carton	in one												
16.	shipper													
17.	Batch details													
18.	shipper label Pasting of BO													
10.	Lasting of Do	Эгт тарс												
Checl	ked by (Produ	ction)												
		1	r		ale here		a a4 ii	41.01 0	1	20:				
	T	1	ın-proc	ess che	ck by p	roducu	on at ini	uai and	every	) IIIII.	1			1
Sr.	In process	Date											<u> </u>	
No.	checks	Time												
1.	Temp.			<u> </u>	<u> </u>								<u> </u>	
2.	RH			<u> </u>	<u> </u>		<u> </u>						<u> </u>	
		J	Prepar	ed By			Che	cked B	y		A	pprove	d By	
Sign	nature													
Sign														
Date	e													



		В	ATCH	PACK	ING R	RECOI	RD								
Prod	uct Code:						BPR N	o.:			<u> </u>				
Prod	uct Name:						Generi	c Nam	e: Telmis	sartan	Tablet	s IP 80	mg		
Effec	tive Date:									Pa	ige No.	: 14 of	24		
Batcl	h No.:				В	atch S	ize:			St	Supersedes No.: Nil				
3.	Forming rolle temperature														
4.	Sealing roller Temperature														
5.	Check working NFD by remove tablet from track	oving m each													
6.	Tab. with for black particle														
7.	Foil shifting														
8.	Batch detail of														
9.	No. of tab/ B														
10.	Proper cutting Blister	g of													
11.	Leak test (Hourly)														
12.	Proper gluing carton														
13.	No. of Blister printed cartor	ı													
14.	Batch detail of printed carton	ı													
15.	Seal the carto														
16.	No. of carton shipper														
17.	Batch details shipper label														
18.	Pasting of BO	OPP tape													
Checl	ked by (Produ	ction)													
		1	In-proce	ess chec	k by pr	oductio	on at ini	tial and	l every 30	min.					
Sr.	In process	Date			- J F								<u> </u>		
		I	Prepare	ed Bv			Che	cked B	v		Ar	prove	d Bv		
Sign	nature		11701										<b>-</b> J		
Date	e														



PRODUCTION DEPARTMENT

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Product Code:	BPR No.:	·
Product Name:	Generic Name: T	elmisartan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 15 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

		1		T	T	Г	П	Г	Г	Г	
No.	checks	Time									
1.	Temp.										
2.	RH										
3.	Forming roller temperature										
4.	Sealing roller Temperature										
5.	Check working of NFD by removing one tablet from each track										
6.	Tab. with fore black particle										
7.	Foil shifting										
8.	Batch detail or	n foil									
9.	No. of tab/ Blister										
10.	Proper cutting Blister	g of									
11.	Leak test (Hourly)										
12.	Proper gluing carton										
13.	No. of Blister printed carton										
14.	Batch detail or printed carton										
15.	Seal the cartor cello tape										
16.	No. of carton shipper										
17.	Batch details of shipper label	on								 	
18.											
Check	xed by (Produc	etion)									

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:	
Product Name:	Generic Name: T	elmisartan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 16 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

### In-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											
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 o	n foil										
9.	No. of tab/ Bl											
10.	Proper cutting Blister	of										
11.	Leak test (Hourly)											
12.	Proper gluing carton											
13.	No. of Blister printed carton											
14.	Batch detail or printed carton											
15.	Seal the cartor cello tape											
16.	No. of carton shipper											
17.	Batch details of shipper label											
18.	Pasting of BO											
Check	Checked by (Production)											

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:	
Product Name:	Generic Name: T	Celmisartan Tablets IP 80 mg
<b>Effective Date:</b>		<b>Page No.:</b> 17 of 24
Batch No.:	Batch Size:	Supersedes No.: Nil

Attach additional sheet if required....

### 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 workin NFD by remo one tablet from track	ving n each							
6.	Tab. with fore black particle	ign /							
7.	Foil shifting								
8.	Batch detail on foil								
9.	No. of tab/ Bl								
10.	Proper cutting Blister	of							
11.	Leak test (Bi-hourly)								
12.	Proper gluing carton								
13.	No. of Blister printed carton								
14.	Batch detail of printed carton								
15.	Seal the cartor cello tape								
16.	No. of carton shipper								
17.	Batch details on shipper label								
18.	18. Pasting of BOPP tape								
Checl	ked by (IPQA)								

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

<b>Product Code:</b>	BPR No.:	BPR No.:					
Product Name:	Generic Name: Telmisa	Generic Name: Telmisartan Tablets IP 80 mg					
Effective Date:		<b>Page No.:</b> 18 of 24					
Ratch No ·	Ratch Size	Supersedes No · Nil					

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

In process checks	_												
1.   Temp.   2.   RH   3.   Forming roller   temperature   4.   Sealing roller   Temperature													
2. RH			Time										
3.   Forming roller temperature		Temp.											
10   10   10   10   10   10   10   10	2.												
Temperature Check working of NFD by removing one tablet from each track  Tab. with foreign / black particle  Poil shifting Batch detail on foil  No. of tab/ Blister  Leak test (Bi-hourly)  Proper gluing of carton  No. of Blister in one printed carton  Batch detail on printed carton  Seal the carton with cello tape  No. of carton in one shipper label  Batch details on shipper label	3.	temperature	r										
5. NFD by removing one tablet from each track  6. Tab. with foreign / black particle  7. Foil shifting  8. Batch detail on foil  9. No. of tab/ Blister  10. Proper cutting of Blister  11. (Bi-hourly)  12. Proper gluing of carton  13. No. of Blister in one printed carton  14. Batch detail on printed carton  15. Seal the carton with cello tape  16. No. of acton in one shipper  17. Batch details on shipper label	4.	Temperature											
Description of the component of the co	5.	NFD by remove one tablet from track	ving n each										
8. Batch detail on foil 9. No. of tab/ Blister 10. Proper cutting of Blister 11. Leak test (Bi-hourly) 12. Proper gluing of carton 13. No. of Blister in one printed carton 14. Batch detail on printed carton 15. Seal the carton with cello tape 16. No. of carton in one shipper 17. Batch details on shipper label	6.		ign /										
9. No. of tab/ Blister 10. Proper cutting of Blister 11. Leak test (Bi-hourly) 12. Proper gluing of carton 13. No. of Blister in one printed carton 14. Batch detail on printed carton 15. Seal the carton with cello tape 16. No. of carton in one shipper 17. Batch details on shipper label	7.	Foil shifting											
10. Proper cutting of Blister  11. Leak test (Bi-hourly)  12. Proper gluing of carton  13. No. of Blister in one printed carton  14. Batch detail on printed carton  15. Seal the carton with cello tape  16. No. of carton in one shipper  17. Batch details on shipper label	8.	Batch detail on foil											
Blister  11. Leak test (Bi-hourly)  12. Proper gluing of carton  13. No. of Blister in one printed carton  14. Batch detail on printed carton  15. Seal the carton with cello tape  16. No. of carton in one shipper  17. Batch details on shipper label	9.	No. of tab/ Blister											
11. (Bi-hourly) 12. Proper gluing of carton 13. No. of Blister in one printed carton 14. Batch detail on printed carton 15. Seal the carton with cello tape 16. No. of carton in one shipper 17. Batch details on shipper label	10.	Proper cutting Blister	of										
12. carton 13. No. of Blister in one printed carton 14. Batch detail on printed carton 15. Seal the carton with cello tape 16. No. of carton in one shipper 17. Batch details on shipper label	11.	(Bi-hourly)											
13. printed carton  14. Batch detail on printed carton  15. Seal the carton with cello tape  16. No. of carton in one shipper  17. Batch details on shipper label	12.	carton											
14. printed carton  15. Seal the carton with cello tape  16. No. of carton in one shipper  17. Batch details on shipper label	13.	printed carton											
16. No. of carton in one shipper Batch details on shipper label	14.	printed carton											
16. shipper  17. Batch details on shipper label	15.	cello tape											
17. shipper label	16.	shipper											
18. Pasting of BOPP tape	17.		on										
	18.	Pasting of BO	PP tape							_			

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

### BATCH PACKING RECORD

<b>Product Code:</b>		BPR No.:									
<b>Product Name:</b>			Generic Name: Telmisartan Tablets IP 80 mg								
<b>Effective Date:</b>		<b>Page No.:</b> 19 of 24									
Batch No.:		Batch	Size:				Supersedes No.: Nil				
Checked by (IPQA)											

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

	Ι_	D 4						
Sr.	In process	Date						
No.	checks	Time						
1.	Temp.							
2.	RH							
3.	Forming roller temperature	•						
4.	Sealing roller Temperature							
5.	Check workin NFD by remove one tablet from track	ving n each						
6.	Tab. with fore black particle	ign /						
7.	Foil shifting							
8.	Batch detail or	n foil						
9.	No. of tab/ Bli	ster						
10.	Proper cutting Blister	of						
11.	Leak test (Bi-hourly)							
12.	Proper gluing carton							
13.	No. of Blister printed carton							
14.	Batch detail or printed carton							
15.	Seal the cartor cello tape							
16.	No. of carton ishipper	in one						

	Prepared By	Checked By	Approved By
Signature			
Date			_



PRODUCTION DEPARTMENT

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	D.		IACI		RECO	ΚD							
Product Code: BPR No.:													
Product Name:				Generi	ic Nam	e: Telm	nisarta	n Tablet	s IP 80	mg			
Effec	ctive Date:								P	age No.	: 20 of	24	
Batcl	h No.:				Batch S	ch Size: Su			Supersedes No.: Nil				
17.	Batch details on shipper label												
18.	Pasting of BOPP tape												
Checked by (IPQA)													

Attach additional sheet if required....

**6.0 SHIPPER WEIGHING RECORD:**Weight limit for filled shipper: \_\_\_\_\_ Kg to \_\_\_\_ Kg

Shipper No.	Gross wt. In Kg.	Weighing done by	Shipper No.	Gross wt. In Kg.	Weighing done by
1.			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.		
17.			42.		
18.			43.		

	Prepared By	Checked By	Approved By
Signature			
Date			



PRODUCTION DEPARTMENT

#### **BATCH PACKING RECORD**

<b>Product Code:</b>	BPR No.:			
<b>Product Name:</b>	Generic Name: Telmisar	Generic Name: Telmisartan Tablets IP 80 mg		
<b>Effective Date:</b>		<b>Page No.:</b> 21 of 24		
Batch No.:	Batch Size:	Supersedes No.: Nil		

Shipper No.	Gross wt. In Kg.	Weighing done by	Shipper No.	Gross wt. In Kg.	Weighing done by	
19.			44.			
20.			45.			
21.			46.			
22.			47			
23.			48.			
24.						
25.						
Min. Shipper V	Min. Shipper Weight:			Max. Shipper Weight:		
Checked By (Production Supervisor)			Verify By (IPQA)			
		_				

Loose Shipper No.:
7.0 RECONCILIATION OF PACKING MATERIAL

Sr. No.	Material	Printed Aluminum foil	Base foil	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				
Check	ked 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): \_\_\_\_\_

	Prepared By	Checked By	Approved By
Signature			
Date			



	BATCH PAC	KING RECORD		
Product	t Code:	BPR No.:		
Product		Generic Nam	e: Telmisartan T	ablets IP 80 mg
Effectiv	e Date:	l l		e <b>No.:</b> 22 of 24
Batch N	lo.:	Batch Size:		ersedes No.: Nil
Samp	oling Details:			
Sr. No.	Sample detail	Quantity		Sampled By
1.	Sample for analysis			
2.	Control Samples			
3.	Stability Samples			
4.	Validation samples			
5.	Other sample			
Tran	SHED GOODS TRANSFER TO F sfer finished goods to FG Stores. Th		copy of T.T. to BP	R
	o. of shippers packed			
	shipper			
	Blister per Carton			
	Γablets transferred to BSR			
	hippers transferred to BSR			
	r note No.			
Sign of	Packing Supervisor			
Sign of	BSR Supervisor			
10.0 BAT	TCH 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		

	Prepared By	Checked By	Approved By
Signature			
Date			



<b>Product Co</b>	de:		BPR No.:	BPR No.:		
Product Na	me:		Generic Name:	Telmisartan 7	Γablets IP 80 mg	
Effective Da	ate:		·	Pag	ge No.: 23 of 24	
Batch No.:		Ba	Satch Size: Supersedes No.: Nil			
5.	Sample					
5a.	Analysis Sample Q	ty.				
5b.	Control Samples Q	ty.				
5c.	Stability Sample Q	ty.				
	Validation Sample					
6.	Total packed Quant	tity (4+5a+5b+5c+5d)				
7.	Accountability=					
Yield = Total Quantity Packed (6) + Partial x 100  Batch size  = x 100  = % (NLT 97.0 %)  Remark: (Packing Superviser) (IPQA)						
Deviation No	0.	Reason for deviation	1			
12.0 REVIE	W OF BPR:		Date: _			
	Particulars	5	Status		Checked By QA	
Signature of	Authorized Persons					
Contents an	d Enclosures:					
PM Requisiti	ion					
PM Issue Or	der					
Excess material issue note, if any						
PM return note (if applicable)						
Specimens of Packing material						
In Process packing control reports						
TR of Finish	ed Product Pack					
	Pro	epared By	Checked By		Approved By	
Signature						
Date						



me: Telmisar	tan Tablets IP 80 mg Page No.: 24 of 24 Supersedes No.: Nil		
me: Telmisar	<b>Page No.:</b> 24 of 24		
	Supersedes No.: Nil		
	l e e e e e e e e e e e e e e e e e e e		
.Y) Batch No	»:		
A.R. No:			
РАТСН.			
ate:			
sion No.	Reason of revision		
	New BPR		
)(	SPATCH.  Oate:  ision No.		

	Prepared By	Checked By	Approved By
Signature			
Date			