	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 1 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

Location:	
Block: Production Tablets (PT)	
Label Claim:	Each film coated tablet contains: Telmisartan IP…….…. 80 mg Excipients ……q.s. Colour: Red Oxide of Iron
Mfg. Lic. No.:	
Product Lic. No.:	**NA**
Self-Life:	24 Months
MFR No.:	
Mfg. Date:	
Exp. Date:	
BMR Issued No.:	
Party:	

Issued By Stamp & Sign.

Responsibility	Name	Designation	Sign	Date
Prepared By				
Checked By				
Approved By				

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 2 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

1.0 MASTER FORMULA:

BILL OF RAW MATERIALS

Sr. No.	Ingredients	Spec.	Qty. In mg Per Tablet	Overages %	Std. Qty. for 1 Lac. In Kg
Raw Material for Dry Mixing:					
Active Ingredients-					
1.	Telmisartan	IP	80.00	-----	8.00#
Inactive Ingredient					
2.	Microcrystalline Cellulose (Avicel PH-102)	IP	30.00	-----	3.000
3.	Palaxmer-188	IP	23.00	-----	2.300
4.	Mannitol	IP	30.00	-----	3.000
5.	Meglumine	IP	76.00	-----	7.600
6.	Crospovidone	IP	15.00	-----	1.500
Raw Material for Binder Preparation-					
7.	PVPK-30	IP	10.00	-----	1.000
8.	Isopropyl Alcohol	IP	150.00	-----	15.000
Raw Material for Blending & Lubrication-					
9.	Cross Carmellose Sodium (CCS)	IP	13.50	-----	1.350
10.	Microcrystalline Cellulose (Avicel PH 102)	IP	10.00	-----	1.000
11.	Talc	IP	5.00	-----	0.500
12.	Magnesium Stearate	IP	7.50	-----	0.750
	Weight of Uncoated Tablets		**300.00 mg**		**30.000 Kg**
Raw Materials for Coating-					
13.	Red Oxide of Iron Redimix (ROI 0510)	IH	9.00	-----	0.900
14.	Isopropyl Alcohol	IP	50.00	-----	5.000
15.	Methylene Dichloride (MDC)	IP	70.00	-----	7.000
	Weight of Coated Tablets		**309.00 mg**		**30.900 Kg**

Note: # Telmisartan IP adds after calculation if assay below 100%.

	Prepared By	Checked By	Approved By
Signature			
Date			

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 3 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

CALCULATION SHEET

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

Note: If assay of API is above 100.0% calculation not required.

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

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

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

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

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

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

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

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

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

Assay calculation:

	Prepared By	Checked By	Approved By
Signature			
Date			

	PHARMA DEVILS PRODUCTION DEPARTMENT	
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Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

Sign/ Date		
Department	**Done by(Production)**	**Checked by (Q.A.)**

2.0 GENERAL INSTRUCTIONS:

- Current version of SOPs should be referred during operation.
- Dispensed raw material/bulk blend/ compressed tablets should be manufactured and stored at temperature not exceeding 27°C and RH NMT 55%
- In all the processing activities, nose mask, hand gloves, secondary gown etc. shall be wearied by the personnel.
- Attach all dispensing tags and cleaning status labels with BMR.
- Clean the equipment's after use as per the standard operating procedure.
- The Blend should be compressed within 15 days.
- The compressed tablets should be packed within 30days.

2.1 Line clearance of Dispensing:

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

Sr. No.	Instructions	Yes/No/NA
1.	Is dispensing area clean and free from any materials of previous batches?	
2.	Whether balance is calibrated and have status label.	
3.	Scoops to be used for dispensing are clean.	
4.	LAF properly working and dispensing booth clean.	
5.	Air differential pressure, temperature and humidity with in limit (if applicable) Temp. ---------- ºC(NMT 27ºC), RH----------% (NMT 55.0%), DP……..(6 to 10 Pascal)	
6.	Material shall be least exposed to atmosphere.	
7.	Ensure proper gowning before entering to the dispensing area, suitable nose mask and surgical gloves shall be used while handling the material.	

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

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

	Prepared By	Checked By	Approved By
Signature			
Date			

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 5 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

	Prepared By	Checked By	Approved By
Signature			
Date			

Pharma Devils	PHARMA DEVILS PRODUCTION DEPARTMENT	

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 6 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

Sr. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	@Req. Qty. In Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
						Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-											
Active Ingredients-											
1.	Telmisartan IP	8.00#									
Inactive Ingredients-											
2.	Microcrystalline Cellulose (Avicel PH 102) IP	3.000									
3.	Palaxmer-188 IP	2.300									
4.	Mannitol IP	3.000									
5.	Meglumine IP	7.600									
6.	Crospovidone IP	1.500									
Raw Material for Binder Preparation-											
7.	PVPK-30 IP	1.000									
8.	Isopropyl Alcohol (IPA) IP	15.00									
Raw Material for Blending & Lubrication-											
9.	Cross Carmellose Sodium (CCS) IP	1.350									
10.	Microcrystalline Cellulose (Avicel PH 102) IP	1.000									
11.	Talc IP	0.500									
12.	Magnesium Stearate IP	0.750									
Raw Materials for Coating-											
13.	Red Oxide of Iron Redimix (ROI 0510) IH	0.900									
14.	Isopropyl Alcohol (IPA) IP	5.000									
15.	Methylene Dichloride (MDC) IP	7.000									

Note: # Telmisartan IP adds after calculation if assay below 100%.
@ Calculate the materials as per required batch size.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

Pharma Devils	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 7 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

Sr. No.	Ingredients	Std. Qty. for 1 Lac. In Kg	@Req. Qty. In Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. By Store	Chkd. By	
						Gross	Tare	Net		Prod.	QA
Raw Material for Dry Mixing-											
Active Ingredients-											
1.	Telmisartan IP	8.00#									
Inactive Ingredients-											
2.	Microcrystalline Cellulose (Avicel PH 102) IP	3.000									
3.	Palaxmer-188 IP	2.300									
4.	Mannitol IP	3.000									
5.	Meglumine IP	7.600									
6.	Crospovidone IP	1.500									
Raw Material for Binder Preparation-											
7.	PVPK-30 IP	1.000									
8.	Isopropyl Alcohol (IPA) IP	15.00									
Raw Material for Blending & Lubrication-											
9.	Cross Carmellose Sodium (CCS) IP	1.350									
10.	Microcrystalline Cellulose (Avicel PH 102) IP	1.000									
11.	Talc IP	0.500									
12.	Magnesium Stearate IP	0.750									
Raw Materials for Coating-											
13.	Red Oxide of Iron Redimix (ROI 0510) IH	0.900									
14.	Isopropyl Alcohol (IPA) IP	5.000									
15.	Methylene Dichloride (MDC) IP	7.000									

Note: # Telmisartan IP adds after calculation if assay below 100%.
@ Calculate the materials as per required batch size.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

Dispensed by **Checked by** **Verified by**
Stores **Production** **QA**
Date **Date** **Date**

2.2 Weight Verification sheet:

Balance ID: _____

Sr. No.	Ingredients	Spec.	UOM	Std. Quantity (Kg)	A.R. No.	Issued Qty. Gr. wt.	Checked By (Production)	Verified by (IPQA)
MATERIAL FOR GRANULATION:								
1.	Telmisartan	IP						
2.	Microcrystalline Cellulose (Avicel PH 102)	IP						
3.	Palaxmer-188	IP						
4.	Mannitol	IP						
5.	Meglumine	IP						
6.	Corospovidone	IP						
7.	PVPK-30	IP						
8.	IPA	IP						
MATERIAL FOR BLENDING & LUBRICATION:								
1.	Cross Carmelllose Sodium (CCS)	IP						
2.	Microcrystalline Cellulose (Avicel PH 102)	IP						
3.	Talc	IP						
4.	Magnesium Stearate	IP						

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 9 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

3.0 GRANULATION PROCESS:

Date: _____ **Granulation started at: _____**

3.1 Line clearance of Granulation:

Previous product: _____, Batch No.:_____

Cleaning done by: _____, Cleaned On: _____,

Sr. No.	Instructions	Yes/No/NA	Checked By (Production)	Verified By (IPQA)
1	Ensure that all equipment and utensils are clean and dry and status board affixes (Record as per Table-1).			
2	Is area free from any materials of previous batch?			
3	Whether the container, sieve, scoops and auxiliary items are cleaned.			
4	Check the room temperature. Temp……..ºC (NMT 27ºC) and Differential pressure ……. Pascal (6 to 10 Pascal).			
5	AHU system under operation or not.			
6	Calibration status of Equipment/instrument complies or not.			
7	Balance calibration status is OK or not.			
8	Whether swab/rinse sample testing report complies or not? (if applicable)			
9	Whether the wall, floor and light in satisfactory condition?			

EQUIPMENT STATUS CHECKLIST

Sr. No.	Name of Equipment	Equipment ID No.	Observation (Should be clean and dried)	Checked (Production)	Verified By (IPQA)
1.	Sifter		Yes/No		
2.	Mass Mixture		Yes/No		
3.	Tray Dryer		Yes/No		

	Prepared By	Checked By	Approved By
Signature			
Date			

4.	Blender		Yes/No		
5.	Balance		Yes/No		
6.	S.S Scoop		Yes/No		

3.2 Sifting: Sift separately the following material and collect in poly bags/containers. Check sieve integrity before and after use.

SIFTING OF GRANULATION MATERIALS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd. By/ Date
			Before Use	After use				
Telmisartan								
Microcrystalline Cellulose (Avicel PH 102)								
Palaxmer-188								
Mannitol								
Meglumine								
Corospovidone								
PVPK-30								

SIFTING OF BLENDING / LUBRICANTS MATERIAL

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd. By/ Date
			Before Use	After use				
Cross Carmelllose Sodium (CCS)								
Microcrystalline Cellulose (Avicel PH 102)								
Talc								
Magnesium Stearate								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

3.3 MANUFACTURING PROCESS:

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Binder preparation-**					
	In S.S Container take **Isopropyl Alcohol** _____ Lts. and dissolve **PVPK-30** (_____ Kg) completely.					
	Qty. of **IPA** ____ liters.					
3.2.2	**Dry Mixing-**					
	Add **Telmisartan** (____# Kg), **Microcrystalline Cellulose (Avicel PH 102)** (_____Kg)**, Palaxmer-188** (_____ Kg)**, Mannitol** (_____ Kg), **Meglumine** (_____ Kg) and **Crospovidone** (_____Kg) in a mass mixture and run at slow speed for 20 minutes.					
3.3.3	**Wet granulation:**					
	Start the mass mixture at slow speed and add the binder paste slowly at the solution addition port. After complete addition of total quantity of binder solution, start at slow speed and mix for as per required time.					
3.3.4	**Drying:**					
	Dry the granules till **IPA** remove and then pass the semi dried granules through ___ mesh sieve. Again dry the granules at 45 to 75°C for final drying.					
	Temperature: _____°C					
	Collect the granules from 5 different places of the tray and check loss on drying.					
	LOD _____%w/w. Recommended LOD: (NMT 2.0 % w/w)					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
3.3.5	**Blending & Lubrication:**					
	Add **Cross Carmellose Sodium (CCS)** (_____Kg), **Microcrystalline Cellulose (Avicel PH 102)** (_____ Kg) and **Talc** (_____Kg) in blender with dried granules and mix it for 20 minutes.					
	Add **Magnesium Stearate** (_____Kg) in blender and mix for further for 5 minutes.					

3.4 GRANULE WEIGHING RECORD:

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

3.5 SAMPLING OF BLEND:

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

_____
Checked By (Production)

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

	Prepared By	Checked By	Approved By
Signature			
Date			

_____
Verified By (IPQA)

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

3.6 YIELD RECONCILIATION:

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

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

C = Samples = ….. ……..

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

Loss Quantity: _____

Checked by (Production): **Verified by (QA):**
Date: **Date:**

4.0 COMPRESSION:

Date: _____ **Started at: _____**

4.1 Line clearance:

Previous product: _____, Batch No.:_____

Sr. No.	Instructions	Observations	Checked (Production)	Verified By (IPQA)
1	Is area free from any materials of previous batch?	Yes/No		
2	Whether area and utensils cleaned?	Yes/No		
3	Whether the compression machine is cleaned and set as per SOP and have "CLEANED" label affixed? **Equipment ID No.: _____**	Yes/No		
4	Check the room temperature, RH and differential pressure =……ºC (NMT 27ºC), RH=…… % (NMT 55%). Differential Pressure……..Pascal (6 to 10 Pascal)	OK/NOT OK		
5	All the equipment shall be used during process are cleaned.	Yes/No		

4.2 Process:

Sr. No.	Compression Instruction	Observations	Checked (Production)	Verified By (IPQA)

	Prepared By	Checked By	Approved By
Signature			
Date			

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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

Table: A-Die and punch verification

Punch Specification																								
Punch Details	Type	Prism: B-Tooling & __-Stations.																						
	Upper Punches	Diameter : 9.5 mm (SC round plain)																		Dies : 9.6 mm				
	Lower Punches	Diameter : 9.5 mm (SC round plain)																						
Upper Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											
Lower Punches	Punch No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
	Punch No.	24	25	26	27	28	29	30	31	32	33	34	35											

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

4.3 IN PROCESS CHECKS:

4.3.1 Specification:

Sr. No.	Parameters	Requirement	Frequency of Monitoring
1.0	Description	SC round shape plain both side	At the start of machine
2.0	Weight of 20 tablets	6.00 gm ± 3%	Every 30 Minutes
3.0	Avg. weight	300 mg ± 5%	Every 2 Hours
4.0	Uniformity of weight	300 mg ± 5%	Every 2 Hours
5.0	Thickness	____ ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3.00 Kg/cm^2	Every 2 Hours
7.0	Friability	NMT 1%	Every 2 Hours
8.0	DT	NMT 15 min	Every 2 Hours
9.0	Diameter	9.5 mm ± 0.2 mm	At the start of machine
10.0	Appearance	White or off colour round shape tablets and plain both side	Every 2 Hours
11.0	Temperature	NMT 27ºC	Every 2 Hours
12.0	RH	NMT 55%	Every 2 Hours

4.4 In-process observation sheet for production:

Description:											
Diameter:											
Wt. of 20 Tabs. 6.00 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 6.00 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness	**Date**										

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

___mm ± 0.2 mm	**Time**										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT	LHS										
NMT 15 min	RHS										
Appearance White or off white colour round shape and plain both side.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required…

WEIGHT VARIATION OF 20 TABLETS

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

Date:								
Time:								
1.								
2.								
3.								
4.								
5.								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
Avg. wt.								
Min. wt.								
Max. wt.								
Checked by								

Attached additional sheet if required…….

4.5 In-process observation sheet for IPQA:

Description:											
Diameter:											
Wt. of 20 Tabs. 6.00 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs.	**Date**										

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
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Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

6.00 gm ± 3%	**Time**										
	LHS										
	RHS										
Thickness ___mm ± 0.2 mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT	LHS										
NMT 15 min	RHS										
Appearance White or off white colour round shape and plain both side.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required……..

WEIGHT VARIATION OF 20 TABLETS

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

Date:								
Time:								

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 19 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

Attached additional sheet if required……..

4.6 TABLET WEIGHING RECORD:

Container No.	Gross wt.	Tare wt.	Net wt.	Container No.	Gross wt.	Tare wt.	Net wt.
1/				11/			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 20 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

2/				**12/**			
3/				**13/**			
4/				**14/**			
5/				**15/**			
6/				**16/**			
7/				**17/**			
8/				**18/**			
9/				**19/**			
10/				**20/**			
Total net weight of Tablets:							
Checked By(Sign & Date):							

4.7 SAMPLING :

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

_____
Checked By (Production)

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

_____
Checked By (IPQA)

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

4.8 YIELD RECONCILIATION:

- Average weight of tablets (A)=: mg
- Total weight of compressed tablets (B) = Kg.
- Quantity of compressed tablet in Number (C)= $\frac{B}{A}$ X 1000 X1000 =
- Samples (D)=
- Yield= $\frac{C + D}{\text{Actual batch size}}$ x 100= **(Yield NLT: 98.50%)**

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

Loss Qty.: _____ Kg.

5.0 COATING: **Date:_____**

	Prepared By	Checked By	Approved By
Signature			
Date			

Pharma Devils	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 21 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

5.1 Line clearance

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

Sr. No.	Instructions	Observations	Checked By	
			Production	QA
1	Ensure that Colloid mill, SS Tank, 100# sieve, coating pan, Spray gun and scoop are cleaned.	Yes/NA/NO		
2	Is area free from any materials of previous batch?	Yes/NA/NO		
3	Whether the scoops and auxiliary items are cleaned.	Yes/NA/NO		
4	Check the room temperature. Temp……..ºC (NMT 27ºC). & RH ……% (NMT 55%)	-		
5	Whether the Auxiliary items are cleaned.	Yes/NA/NO		
6	Whether the coating pan is cleaned and set as per SOP and have “CLEANED” label affixed.	Yes/NA/NO		
7	Balance calibration status is OK or not.	Yes/NA/NO		
8	Whether tablet approved or not?	Yes/NA/NO		
Differential pressure across RLAF and Room:		(Limit (Between 5to15 Pascal)		
Checked By:(Production):		**Verified By:(IP/QA)**		
Sign and Date:		**Sign and Date:**		

5.2 COATING PROCESS:

Equipment ID to be used: _____, _____, _____, Coating started on: _____

	Instructions	Std. time (min)	Observed time		Done By) (Sign & Date)	Checked By (Sign & Date)	Remarks
			From	To			
Solution preparation	Homogenize Pass the solution in homogenizer to uniform suspension to avoid inclusion of air bubbles. Filter the suspension through ____ # cover the prepared suspension in the vessel securely for use before coating. The dispersion, if required; Pass through200 # muslin cloth.	-					
	Keep aside with lid cover. Ensure Coating solution should be free from air bubbles.	-					
	Cover the prepared solution in the vessel securely for use before coating with labels affixed on vessel mentioning batch details.						
Coating of Tablet	Take sorted tablet in coating room	-					
	Fit the spray gun with 1.5mm diameter nozzle and set the atomizing air pressure at 2.5-4.0 kg/cm2. Start the exhaust system.	-					
	Transfer the tabs. to conventional coating pan and start rolling the pan (at RPM……..) and pre warm the tabs to obtain the bed temperature (_____ºC).	-					

	Prepared By	Checked By	Approved By
Signature			
Date			

	Start the spraying solution over the tablet and let them be dry immediately.	-					
	After drying unload the coating tablets in pre-tare Polybag lined drum with status label.	-					
	Check and record the physical parameters of coated tablets as per given check sheet.	-					

5.3 COATING INPROCESS CHECKS: (Record the observation every half an hour)

Parameter	**Limit**	**Date**								
		Time								
Pan Speed	4 to 5 RPM									
Inlet Air Temperature	65to 75^0 C									
Peristaltic Pump Speed	16 RPM									
Atomizing Air Pressure	2.5 to 4.0Kg/cm^2									
Exhaust Air Temperature	42 to 48^0**C**									
Bed Temperature	40 to50^0**C**									

5.4 PARAMETERS AFTER COATING:

Tests	**Specification**	**Production observation**	**IPQA observation**
Description	Reddish colour round shape tablet plain both side		
Weight of 20 tablets	6.18 gm ± 3%		
Avg. weight	309 mg ± 5%		
Uniformity of weight	309 mg ± 5%		
Disintegration	30 minutes		
Checked by (Production):		**Checked By (IPQA):**	

5.5 WEIGHING RECORD OF COATED TABLETS:

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

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

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 23 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil
Checked By(Sign & Date):		

5.6 VISUAL INSPECTION OF TABLET:

Machine No. _____ Date: _____

Time Duration		Quantity rejected	Done by
From	To		

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

% Yield: _____

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

5.7 SAMPLING:

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

_____
Checked By (Production)

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

_____
Checked By (IPQA)

5.8 YIELD RECONCILIATION:

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

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 80 mg	
Document No.:	**Effective Date:**	**Page No.:** 24 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:** Nil

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

6.0 FINAL REVIEW OF BATCH CARD ON SHOP FLOOR:

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

_____
Checked By (Prod. Mgr.)

7.0 ANY DEVIATION:

Deviation No.	Reason for deviation

_____
Checked By (Prod. Manager)

8.0 HISTORY SHEET:

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

	Prepared By	Checked By	Approved By
Signature			
Date			