	PHARMA DEVILS PRODUCTION DEPARTMENT	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 1 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets	
Label Claim:	Each film coated tablet contains: Telmisartan IP…….… 20 mg Excipients ……..…q.s. Colour: Titanium Dioxide IP
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 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 2 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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:					
1.	Light Magnesium Dioxide	IP	100.00	-----	10.00
2.	Maize Starch	IP	40.00	-----	4.00
3.	Microcrystalline Cellulose	IP	62.00	-----	6.20
4.	Colloidal Silicon Dioxide (Aerosil)	IP	3.00	-----	0.30
5.	Crosspovidone	IP	10.00	-----	1.00
Raw Material for Binder Preparation-					
Binder-I-					
6.	Sodium Hydroxide	IP	4.00	-----	0.40
7.	Meglumine IP	IP	30.00	-----	3.00
8.	Purified Water	IP	QS	-----	QS
Binder-II-					
9.	Telmisartan	IP	20.00	-----	2.00#
10.	Isopropyl Alcohol (IPA)	IP	80.00	-----	8.00
Raw Material for Lubrication-					
11.	Crosspovidone	IP	10.00	-----	1.00
12.	Colloidal Silicon Dioxide (Aerosil)	IP	2.00	-----	0.20
13.	Magnesium Stearate	IP	8.00	-----	0.80
	Weight of Uncoated Tablets		**289.00 mg**		**28.90 Kg**
Raw Materials for Coating-					
14.	White Colour Redimix (Medicoat Uni WT335)	IH	9.00	-----	0.90
15.	Isopropyl Alcohol (IPA)	IP	80.00	-----	8.00
16.	Methylene Dichloride (MDC)	IP	120.00	-----	12.00
	Weight of coated Tablets		**298.00 mg**		**29.80 Kg**

Note: # Telmisartan IP adds after calculation if assay below 99%.

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 3 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

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

Note: If assay of API is above 99.0% 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 =
	----------%	$\frac{\text{\_\_\_\_\# x 100}}{\text{A1}}$ = ----------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	
BATCH MANUFACTURING RECORD		

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 4 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

Sign/ Date		
Department	**Done by(Production)**	**Verified 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 15 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			

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

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 6 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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-											
Inactive Ingredients-											
1.	Light Magnesium Dioxide IP	10.00									
2.	Maize Starch IP	4.00									
3.	Microcrystalline Cellulose IP	6.20									
4.	Colloidal Silicon Dioxide (Aerosil) IP	0.30									
5.	Crosspovidone IP	1.00									
Raw Material for Binder Preparation-											
Binder-I											
6.	Sodium Hydroxide IP	0.40									
7.	Meglumine IP	3.00									
8.	Purified Water IP	QS									
Binder-II											
9.	Telmisartan IP	2.00#									
10.	Isopropyl Alcohol (IPA) IP	8.00									
Raw Material for Lubrication-											
11.	Crosspovidone IP	1.00									
12.	Colloidal Silicon Dioxide (Aerosil) IP	0.20									
13.	Magnesium Stearate IP	0.80									
Raw Materials for Coating-											
14.	White Colour Redimix (Medicoat Uni WT335) IH	0.90									
15.	Isopropyl Alcohol IP	8.00									
16.	Methylene Dichloride IP	12.00									

Note: # Telmisartan IP adds after calculation if assay below 99%.
@ 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

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 7 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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-											
Inactive Ingredients-											
1.	Light Magnesium Dioxide IP	10.00									
2.	Maize Starch IP	4.00									
3.	Microcrystalline Cellulose IP	6.20									
4.	Colloidal Silicon Dioxide (Aerosil) IP	0.30									
5.	Crosspovidone IP	1.00									
Raw Material for Binder Preparation-											
Binder-I											
6.	Sodium Hydroxide IP	0.40									
7.	Meglumine IP	3.00									
8.	Purified Water IP	QS									
Binder-II											
9.	Telmisartan IP	2.00#									
10.	Isopropyl Alcohol (IPA) IP	8.00									
Raw Material for Lubrication-											
11.	Crosspovidone IP	1.00									
12.	Colloidal Silicon Dioxide (Aerosil) IP	0.20									
13.	Magnesium Stearate IP	0.80									
Raw Materials for Coating-											
14.	White Colour Redimix (Medicoat Uni WT335) IH	0.90									
15.	Isopropyl Alcohol IP	8.00									
16.	Methylene Dichloride IP	12.00									

Note: # Telmisartan IP adds after calculation if assay below 99%.
@ Calculate the materials as per required batch size.

Dispensed by **Checked by** **Verified by**

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 8 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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.	Light Magnesium Dioxide	IP						
2.	Maize Starch	IP						
3.	Microcrystalline Cellulose	IP						
4.	Colloidal Silicon Dioxide (Aerosil)	IP						
5.	Crosspovidone	IP						
6.	Sodium Hydroxide	IP						
7.	Meglumine	IP						
8.	Telmisartan	IP						
9.	Isopropyl Alcohol (IPA)	IP						
MATERIAL FOR BLENDING & LUBRICATION:								
1.	Crosspovidone	IP						
2.	Colloidal Silicon Dioxide (Aerosil)	IP						
3.	Magnesium Stearate	IP						

	Prepared By	Checked By	Approved By
Signature			
Date			

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 15 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.	Shifter		Yes/No		
2.	Mass Mixture		Yes/No		
3.	Tray Dryer		Yes/No		
4.	Blender		Yes/No		
5.	Balance		Yes/No		

	Prepared By	Checked By	Approved By
Signature			
Date			

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				
Light Magnesium Dioxide IP								
Maize Starch IP								
Microcrystalline Cellulose IP								
Colloidal Silicon Dioxide (Aerosil) IP								
Crosspovidone IP								
Sodium Hydroxide IP								
Meglumine IP								
Telmisartan IP								

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				
Crosspovidone								
Colloidal Silicon Dioxide (Aerosil)								
Magnesium Stearate								

	Prepared By	Checked By	Approved By
Signature			
Date			

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 required qty. of **Purified Water** ____ Lts. add and dissolve one by one **Sodium Hydroxide** (_____Kg) and **Meglumine** (_____Kg) completely. Now in another SS container take **IPA** _____ Lts. and dissolve **Telmisartan** (_____#Kg) completely and pour it and mixed it properly with **Sodium Hydroxide** and **Meglumine** solution.					
3.2.2	**Dry Mixing-**					
	Add **Light Magnesium Dioxide** (_____Kg), **Maize Starch** (_____Kg), **Microcrystalline Cellulose** (_____ Kg), **Colloidal Silicon Dioxide (Aerosil)** (_____Kg) and **Crosspovidone** (_____Kg) in a mass mixture and run the impeller at slow speed for 20 minutes.					
3.3.3	**Wet granulation:**					
	Start the impeller of 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 the impeller at slow speed and mix for 5 minutes.					
3.3.4	**Drying:**					
	Dry the granules till **IPA** remove and then pass the semi dried granules through 16# 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.					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 12 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
	LOD _____%w/w. Recommended LOD: (NMT 2.0 % w/w)					
3.3.5	**Blending & Lubrication:**					
	Add **Crosspovidone** (_____Kg) and **Colloidal Silicon Dioxide (Aerosil)** (_____ 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			

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 13 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

_____
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 15 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			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 14 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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	**B**-Tooling & ___ -Stations.																							
	Upper Punches	Diameter: 9.5 mm (Round Shape & Plain)																		Dies: 9.5 mm					
	Lower Punches	Diameter: 9.5 mm (Round Shape & 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												

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

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

4.3 IN PROCESS CHECKS:

4.3.1 Specification:

Sr. No.	Parameters	Requirement	Frequency of Monitoring
1.0	Description	SC round shape tablets plain both side.	At the start of machine
2.0	Weight of 20 tablets	5.78 gm ± 3%	Every 30 Minutes
3.0	Avg. weight	289.00mg ± 5%	Every 2 Hours
4.0	Uniformity of weight	289.00 mg ± 7.5%	Every 2 Hours
5.0	Thickness	____ ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3.0 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 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. 5.78 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 5.78 gm ± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness ____mm ± 0.2mm	**Date**										
	Time										
	LHS										

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 16 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min	LHS										
	RHS										
Appearance White or off white colour round shape tablets 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.								
6.								

	Prepared By	Checked By	Approved By
Signature			
Date			

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. **5.78 gm ± 3%**	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs.	**Date**										
	Time										
	LHS										

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 18 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

5.78 gm ± 3%	RHS										
Thickness ____mm ± 0.2mm	**Date**										
	Time										
	LHS										
	RHS										
Friability (NMT 1 %)	**Date**										
	Time										
	LHS										
	RHS										
Hardness (NLT 3.0 Kg/cm^2)	LHS										
	RHS										
DT NMT 15 min	LHS										
	RHS										
Appearance White or off white colour round shape tablets 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.								

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 19 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

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 COMPRESSED TABLET WEIGHING RECORD:

Container No.	Gross wt.	Tare wt.	Net wt.	Container No.	Gross wt.	Tare wt.	Net wt.
1/				**11/**			
2/				**12/**			
3/				**13/**			
4/				**14/**			
5/				**15/**			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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

6/				**16/**			
7/				**17/**			
8/				**18/**			
9/				**19/**			
10/				**20/**			
Total net weight of Compressed 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.

_____
Verified 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)= $\frac{B \times 1000 \times 1000}{A}$ =
•	Samples (D)=
•	Yield= $\frac{C + D \times 100}{\text{Actual batch size}}$ = **(Yield NLT: 98.50%)**
Checked By (Production):	**Verified By (IPQA):**

Loss Qty.: _____ Kg.

5.0 COATING: **Date: _____**

5.1 Line clearance

Previous product: _____, Batch No.:_____

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 21 of 24
Batch No.:	**Batch Size:**	**Supersedes 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/cm^2. 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).	-					
	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.	-					

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Telmisartan Tablets IP 20 mg	
Document No.:	**Effective Date:**	**Page No.:** 22 of 24
Batch No.:	**Batch Size:**	**Supersedes No.:**

	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 4.0 Kg/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	White or off white colour round shape tablet plain both side.		
Weight of 20 tablets	5.96 gm $\pm$ 3%		
Avg. weight	298.0 mg $\pm$ 5%		
Uniformity of wt.	298.0 mg $\pm$ 7.5%		
Disintegration	NMT 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 coated tablets:							
Checked By(Sign & Date):							

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

5.6 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.

_____
Verified By (IPQA)

5.7 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)

5.8 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%)**

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

	Prepared By	Checked By	Approved By
Signature			
Date			

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			