PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 1 of 19
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Tablets (PT)	
Label Claim:	Each uncoated tablet contains: Amlodipine Besilate IP Eq. to Amlodipine …….. 10 mg Excipients ……q.s. Colour : Sunset Yellow FCF
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:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 2 of 19
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:					
Active Ingredients-					
1.	Amlodipine Besilate	IP	14.5 eq. to 10 mg	----	1.45#
Inactive Ingredients-					
2.	Microcrystalline Cellulose PH-112 (MCCP-112)	IP	89.00	----	8.90
3.	Colour Sunset Yellow Lake	IH	0.30	----	0.03
4.	Sodium Starch Glycolate (Primogel)	IP	1.00	----	0.10
Raw Material for Lubrication-					
5.	Colloidal Silicon Dioxide (Aerosil)	IP	1.25	----	0.125
6.	Talcum Powder	IP	2.00	----	0.20
7.	Sodium Bicarbonate	IP	2.00	----	0.20
8.	Sodium Lauryl Sulphate (SLS)	IP	1.25	----	0.125
9.	Sodium Starch Glycolate (Primogel)	IP	2.50	----	0.25
10.	Magnesium Stearate	IP	1.50	----	0.15
	Weight of Uncoated Tablets		**115.30 mg**		**11.53 Kg**

Note: # Amlodipine Besilate IP add 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:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 3 of 19
Batch No.:	**Batch Size:**	**Supersedes No.:**

CALCULATION SHEET

1- Amlodipine Besilate 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 **Amlodipine Besilate 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 Amlodipine Besilate 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 **Amlodipine Besilate IP** is to be used:

A.R. No. of **Amlodipine Besilate 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 **Amlodipine Besilate IP** to be dispensed = (b1) + (g1) =_____Kg

Assay calculation:

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

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

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
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Batch No.:	**Batch Size:**	**Supersedes No.:**

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…….Pascal (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			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 5 of 19
Batch No.:	**Batch Size:**	**Supersedes No.:**

BILL OF RAW MATERIALS **(PRODUCTION 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.	Amlodipine Besilate IP	1.45#									
Inactive Ingredients-											
2.	Microcrystalline Cellulose PH-112 (MCCP-112) IP	8.90									
3.	Colour Sunset Yellow Lake IH	0.030									
4.	Sodium Starch Glycolate (Primogel) IP	0.100									
Raw Material for Lubrication-											
5.	Colloidal Silicon Dioxide (Aerosil) IP	0.125									
6.	Talcum Powder IP	0.20									
7.	Sodium Bicarbonate IP	0.20									
8.	Sodium Lauryl Sulphate (SLS) IP	0.125									
9.	Sodium Starch Glycolate (Primogel) IP	0.25									
10.	Magnesium Stearate IP	0.15									

Note: # Amlodipine Besilate IP add after calculation if assay below 99%.

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:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 6 of 19
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-											
Active Ingredients-											
1.	Amlodipine Besilate IP	1.45#									
Inactive Ingredients-											
2.	Microcrystalline Cellulose PH-112 (MCCP-112) IP	8.90									
3.	Colour Sunset Yellow Lake IH	0.030									
4.	Sodium Starch Glycolate (Primogel) IP	0.100									
Raw Material for Lubrication-											
5.	Colloidal Silicon Dioxide (Aerosil) IP	0.125									
6.	Talcum Powder IP	0.20									
7.	Sodium Bicarbonate IP	0.20									
8.	Sodium Lauryl Sulphate (SLS) IP	0.125									
9.	Sodium Starch Glycolate (Primogel) IP	0.25									
10.	Magnesium Stearate IP	0.15									

Note: # Amlodipine Besilate IP add after calculation if assay below 99%.

Dispensed by
Stores
Date

Checked by
Production
Date

Verified by
QA
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

2.2 Weight Verification Sheet:

Balance ID: _____

Sr. No.	Ingredients	Spec.	UOM	Std. Quantity (Kg)	A.R. No.	Issued Qty			Checked By (Prod.)	Verified by (IPQA)
						Gr. wt.	Tare wt.	Net wt.		
MATERIAL FOR GRANULATION :										
1.	Amlodipine Besilate	IP								
2.	Microcrystalline Cellulose PH-112 (MCCP-112)	IP								
3.	Colour Sunset Yellow Lake	IH								
4.	Sodium Starch Glycolate	IP								
MATERIAL FOR LUBRICATION:										
1.	Colloidal Silicon Dioxide	IP								
2.	Talcum	IP								
3.	Sodium Bicarbonate	IP								
4.	Sodium Lauryl Sulphate	IP								
5.	Sodium Starch Glycolate	IP								
6.	Magnesium Stearate	IP								

3.0 GRANULATION PROCESS: **Granulation started on:**_____

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?			

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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

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.	SS Container		Yes/No		
4.	Try dryer		Yes/No		
5.	Multimill		Yes/No		
6.	Blender		Yes/No		
7.	Balance		Yes/No		
8.	SS 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				
Amlodipine Besilate								
Microcrystalline Cellulose PH-112 (MCCP-112)								
Colour Sunset Yellow Lake								
Sodium Starch Glycolate								

SIFTING OF BLENDING MATERIAL / LUBRICANTS

Ingredient	Qty. In Kg	Sieve Size (#)	Sieve Integrity		From	To	Done By/ Date	Ckd By/ Date
			Before Use	After use				
Colloidal Silicon Dioxide								
Talcum								
Sodium Bicarbonate								
Sodium Lauryl Sulphate								
Sodium Starch Glycolate								
Magnesium Stearate								

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Amlodipine Tablets IP	
Document No.:	**Effective Date:**	**Page No.:** 9 of 19
Batch No.:	**Batch Size:**	**Supersedes No.:**

3.3 MANUFACTURING PROCESS:

Step No.	Manufacturing Instruction	Eq. ID.	From	To	Done By/ Date	Ckd. By/ Date
3.3.1	**Dry Mixing:**					
	Add **Amlodipine Besilate** (____#Kg), **Microcrystalline Cellulose PH-112** (____Kg), **Colour Sunset Yellow Lake** (____Kg) and **Sodium Starch Glycolate** (____Kg) in a mass mixture and run at slow speed for 20 minutes.					
3.3.2	**Blending & Lubrication:**					
	Add **Colloidal Silicon Dioxide** (____Kg), **Talcum** (____Kg), **Sodium Bicarbonate** (____Kg), **Sodium Lauryl Sulphate** (____Kg) & **Sodium Starch Glycolate** (____Kg) in blender with dry mixing granules and mix it for 20 minutes.					
3.3.3	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					

	Prepared By	Checked By	Approved By
Signature			
Date			

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.

_____
Checked 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)
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			

BATCH MANUFACTURING RECORD

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Table: A-Die and punch verification

Punch Specification																								
Punch Details	Type	**B**-Tooling & _____ Stations.																						
	Upper Punches	6.3 mm (Round shape with break line)																						Dies : 6.4 mm
	Lower Punches	6.3 mm (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											

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	Orange colour round shape tablet with one side break line.	At the start of machine
2.0	Weight of 20 tablets	2.30gm± 3%	Every 30 Minutes
3.0	Avg. weight	115 mg ± 5%	Every 2 Hours
4.0	Uniformity of weight	115 mg ± 7.5%	Every 2 Hours
5.0	Thickness	2.9 ± 0.2 mm	Every 2 Hours
6.0	Hardness	NLT 3 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	6.3 mm± 0.2 mm	At the start of machine
10.0	Appearance	Orange colour round shape tab. with one side break.	Every 2 Hours
11.0	Temperature	NMT 27ºC	Every 2 Hours
12.0	RH	NMT 55%	Every 2 Hours

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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4.4 In-process observation sheet for production:

Description:											
Diameter of tablets:											
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 2.9 ± 0.2 mm	**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: Orange colours round shape tab. with one side break line.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required…

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

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

WEIGHT VARIATION OF 20 TABLETS

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

Date:								
Time:								
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…….

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

BATCH MANUFACTURING RECORD

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4.5 In-process observation sheet for IPQA:

Description:											
Diameter:											
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Wt. of 20 Tabs. 2.30gm± 3%	**Date**										
	Time										
	LHS										
	RHS										
Thickness 2.9 ± 0.2 mm	**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: Orange colours round shape tab. with one side break line.	LHS										
	RHS										
Temperature (NMT 27°C)	----										
RH (NMT 55%)	----										
Done By											

Attached additional sheet if required……..

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

BATCH MANUFACTURING RECORD

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

WEIGHT VARIATION OF 20 TABLETS

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

Date:								
Time:								
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……..

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

4.6 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/			
6/				16/			
7/				17/			
8/				18/			
9/				19/			
10/				20/			
Total net weight of Tablets:							
Checked By(Sign & Date):							

4.7 VISUAL INSPECTION OF TABLET:

Date: _____

Time Duration		Quantity rejected	Done by
From	To		

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

% Yield: _____

Checked by (Production):
(Sign & Date)

Verified by (IPQA):
(Sign & Date)

4.8 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.

4.9 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.

	Prepared By	Checked By	Approved By
Signature			
Date			

5.0 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.)

6.0 ANY DEVIATION:

Deviation No.	Reason for deviation

_____

Checked By (Prod. Manager)

7.0 HISTORY SHEET:

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

	Prepared By	Checked By	Approved By
Signature			
Date			