GMP Software India

104, Garnets Bay, near Shereton Hotel, behind Chandhare Complex, Clover Park, Viman Nagar, Pune, Maharashtra 411014

BATCH MANUFACTURING RECORD			
Product:		B.No.:	Copy No.:
Standard Batch Size : :	Mfg.Date:	Exp.Date:	Page No. Page 1 of 38
Actual Batch Size: Nos			

BATCH MANUFACTURING RECORD

Product Code:		Shelf Life:
BMR Number		Effective Date :
Supersedes BMR Number		Manufacturing Licence No.:
Label Claim: Each Uncoated Tablet Contains: • Paracetamol BP..... 500 mg • Excipient ..... q.s.		**Description:** White circular, flat, uncoated tablets with a break line on one side and the other side plain of each tablet.
Document Issued By QA Officer Sign/Date	Document Checked By Competent Technical Person /Head Production Sign/Date	Document Approve By Head QA/Designee Sign/Date KD -622
Batch Manufacturing Schedule		
	Date of Commencement	Date of Completion
Granulation		
Compression		

Document Revision History		
Version No	Effective Date	Reason For Change:

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 1.0 –CALCULATIONS-

To be prepared by Production Chemist- Calculate the quantity of all ingredients for this batch size as against following standard formula

S r. No	R. M. CODE	Ingredients	Specification	Quantity per tablets		Standard Batch Size 13.75 L	Qty issued for Batch Size	UOM
				label claim mg	Qty with Ovgs mg			
STEP I		**GRANULATION :**						
DRY MIX & WET GRANULATION :								
			TOTAL					**kg**
STEP II		**LUBRICATION :**						

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

GMP Software India

104, Garnets Bay, near Shereton Hotel, behind Chandhare Complex, Clover Park, Viman Nagar, Pune, Maharashtra 411014

Final quantity of Paracetamol & Maize Starch

Sr. No.	R. M. CODE	INGREDIENTS	Specifications	AR No.	Qty issued for Batch Size	UOM
						kg
						kg
						kg

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

2.0 Dispensing of Raw Material

2.1 Line Clearance for Material Dispensing:

- Ensure that dispensing area and Dispensing Laminar Air Flow unit is cleaned properly and there are no traces of Previous product of material.
- Ensure that balance being used are calibrated and verified for calibration.
- Ensure that Temperature and humidity of the area is as prescribed limits.

Previous Product :		Batch No. :	
Area Cleaning Done By :		Checked By :	
Line Clearance Given By QA :		Date :	
Line Clearance SOP Ref No :		Time :	
Pressure differential in Reverse laminar air flow :			
(Limit 10.0 to 25.00 mm of W.G.)			

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

2.2 DISPENSING RECORD (BMR COPY)

Dispensing Date	Time				RLAF			
	Start Time		End Time		Start Time		End Time	

RM Code	Material Name	SPC	LOT	Batch Qty. (Kg)	A.R. No.	Weight in KG			Done By Stores	Checked By Product	Verified By QA
						Gross Wt	Tare Wt	Net Wt			

Total Quantity of Active	
RM Code	Total Batch Qty. (Kg)
RP034	
Total	

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

2.2 DISPENSING RECORD (STORE COPY)

Dispensing Date	Time				RLAF			
	Start Time		End Time		Start Time		End Time	

RM Code	Material Name	SPC	LOT	Batch Qty. (Kg)	A.R. No.	Weight in KG			Done By Stores	Checked By Product	Verified By QA
						Gross Wt	Tare Wt	Net Wt			

Total Quantity of Active	
RM Code	Total Batch Qty. (Kg)
RP034	
Total	

Dispensed Material Transfer Details		
Transferred By Sign/Date	Received By Sign/Date	Checked By Sign/Date

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

General Instruction

1	Ensure that Every Equipment is Cleaned, calibrated and Qualified for use.
2	Ensure that area is cleaned properly.
3	Gloves, nose masks & safety wares are to be worn during manufacturing operations.
4	Every area and equipment shall be Labelled for its status.
5	Ensure proper Line clearance by Quality Unit before starting the operations.
6	Ensure that all the material weights will be checked before addition by competent officer of Production.
7	Containers used for manufacturing shall be cleaned ,covered and labelled properly.
8	All storage conditions shall be followed as per material storage specifications.
9	Each stage of process shall be reconciled and losses shall be reported in BMR.
10	If any deviation, Incident or abnormal process behaviour shall be reported Immediately to QA Department.
11	Wherever necessary sieve integrity shall be checked.

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

List of Equipments to be used for Manufacturing:

Sr. No	Name of Equipment	Capacity	Equipment ID	Operation/Cleaning SOP No

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.0 GRANULATION:

STAGE 3.1 Line Clearance for Granulation:

1 Ensure that Granulation area and all equipments are cleaned properly and there are no traces of Previous product of material.
2 Ensure that balance being used are calibrated and verified for calibration.
3 Ensure that Temperature and humidity of the area is as prescribed limits.

Previous Product		Batch No	
Area Cleaning Done By		Checked By	
Line Clearance Given By QA		Date	
Line Clearance SOP Ref No : SOP/QA/GE/		Time	
Ensure That Temp. Shall NMT 25?C, % RH. Shall NMT 55% during the processing of the materials in Granulation area			

Equipment Cleanliness Checks:

Name of Equipment	Equipment ID	Cleaned By	Checked By
Mechanical Sifter	PD/EQ/005/		
Rapid Mixer Granulator (RMG)	PD/EQ/007/		
Fluidised Bed Dryer (FBD)	PD/EQ/008/		
Multimill	PD/EQ/009/		
Octagonal Blender	PD/EQ/049		
Tipper	PD/EQ/038		

STAGE 3.2 MILLING OF ACTIVE INGRADIENT AND SIFTING OF EXCIPIENTS:

3.2.1 Assemble & Operate Sifter as per SOP No. SOP/PR/EQP/003-02.
3.2.2 Fix the specified mesh in the sifter and place a HDPE drum lined with polythene bag at the discharge end and tie the bag properly.
3.2.3 Sift the materials through respective mesh specified. Collect the sifted materials in polythene bag in HDPE drum.
Note : Pregelatinised Starch (Universal) and Sodium Starch Glycolate (Primogel)of dry mixing to be pass through 60#.
3.2.4 Check the integrity of sifter sieves before and after sifting the materials.
3.2.5 Mill the Paracetamol using 0.5 mm screen. Mill at impact forward Position.

Equipment No:

Material	LOT No	Weight In Kg	Sieve/Mesh Size	Time		Integrity		Done By	Checked By
				Start Time	End Time	Before	After		
	LOT- I								
	LOT- II								
	LOT- III								
	LOT- IV								
	LOT- V								

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.3 DRY MIXING & WET GRANULATION:

3.3.1 Start and Operate RMG as per SOP No. SOP/PR/EQP/004-02
3.3.2 Load the previously milled material from Step - 3.2.5 to RMG and mix at slow speed for 10 minutes. .
3.3.3 Load the previously Sifted material from Step - 3.2.3 to RMG and mix at slow speed for 10 minutes.
3.3.4 Observe ammeter reading to achieve 18A + 0.5A followed by fast mixing and chopper for 5 minutes
3.3.5 Add the 30 kg of Purified water gradually to RMG and mix at slow speed for 10 minutes with Chopper 'off' and at high speed for 10 minutes with Chopper 'on'
3.3.6 Add 2 kg of water for every 10 min till the water volume reaches to 34 kg and mix it at high speed with Chopper 'on'.
3.3.7 After complete addition of water Continue mixing at high speed till granules of desired consistency is obtained and ammeter reading reaches 18A±0.5A If required add additional quantity of water to get granules of desired consistency.

LOT No	Ingredients	Date	Dry Mixing Time		Wet Mixing Time		Ampere Reading	Operator	Checked By Production
			From	To	From	To			
LOT- I									
LOT- II									
LOT- III									
LOT- IV									
LOT- V									

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

DATE	Lot No	Time	Sampling Intimation Given By	@Sample Collected By IPQA	Results Assay(Limits)	A.R.No	Checked By Production Officer
Sampling After Dry Mixing for Assay :							
	Lot- I						
	Lot- II						
	Lot- III						
	Lot- IV						
	Lot- V						
Sampling After Wet Mixing for Assay :							
	Lot- I						
	Lot- II						
	Lot- III						
	Lot- IV						
	Lot- V						

Note : Pregelatinised Starch (Universal) and Sodium Starch Glycolate (Primogel)of dry mixing to be pass through 60#.

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.4 DRYING OF GRANULES

3.4.1 Setup & operate FBD as per SOP No.: SOP/PR/EQP/005-02
3.4.2 Load the granules into FBD bowl and air dry for 20 min For Fluidisation with in between raking.
3.4.3 Set the inlet temperature at 80°C - 85°C.& start the drying . After 10 min of drying
3.4.4 remove FBD Bowel and rake the granules in FBD Bowel also scrap the materials from the sides of FBD Bowel
3.4.5 Continue drying until the LOD of dried granules reaches in between 2.0-2.6% w/w when checked on IR Balance at 105°C for 10 min.
3.4.6 Remove FBD trolley & take granules for sifting.
3.4.7 Repeat the above procedure for all other lots..

Lot	Date	Drying Time		Parameters				LOD	Checked by
LOT-I									
LOT-II									
LOT-III									
LOT-IV									
LOT-V									

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.5 SIFTING MILLING OF DRY GRANULES

3.5.1 Assemble & Operate Sifter as per SOP No. SOP/PR/EQP/003-02.

3.5.2 Pass the dried granules through 16# mesh S.S Screen fitted with Mechanical Sifter and collect them in HDPE drums lined with polyethylene bags.

3.5.3 Collect the oversize granules retained on the 16# S.S. Screen and pass it through 2.0 mm screen of Multi Mill at medium speed, knife forward position and collect the milled granules in HDPE drums lined with polyethylene bags.

3.5.4 remove FBD Bowel and rake the granules in FBD Bowel also scrap the materials from the sides of FBD Bowel

3.5.5 Pass the milled granules through 16# mesh S.S Screen fitted with Mechanical Sifter and collect them in HDPE drums lined with polyethylene bags.

SIFTING DETAILS	MILLING DETAILS
Equipment ID :	Equipment ID:

	Time		Sieve integrity		Done By	Checked By	Time		Screen Integrity		Done By	Checked By
I												
II												
III												
IV												
V												

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 3.6 DRY GRANULES WEIGHING RECORD

Weighing Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				
No of Containers					Weighing Checked By/Sign Date				
Total Weight of Granules (KG)									

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 3.7 Line Clearance for Blending and Lubrication :

Previous Product	:		Batch No.	:	
Area Cleaning Done By	:		Checked By	:	
Line Clearance Given By QA	:		Date	:	
Line Clearance SOP Ref No	:		Time	:	

Note: Ensure That Temp. Shall NMT 25°C, % RH. Shall NMT 55% during the processing of the materials in Compression area.

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.8 SIFTING OF LUBRICATING AGENTS

3.8.1 Assemble & Operate Sifter as per SOP No: SOP/PR/EQP/003-02.
3.8.2 Pass the lubricants through 60# mesh S.S Screen fitted with and collect them in HDPE drums lined with LDPE bags.

Sr. No.	Item	Qty For 13.75 L	Qty(Kg)	Mesh	Date	Sifting time		Mesh Integrity		Done by	Checked by
						From	To	Before	After		
LUBRICATION MATERIAL											

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STAGE 3.9 BLENDING WITH LUBRICATION OF DRIED (sifted) GRANULES

3.9.2 Load the dried granules from step 3.6 and add sifted lubricants except Magnesium Stearate step 3.8 into Octagonal Blender and Close the lid of Octagonal Blender and mix for 20 minutes

3.9.3 Then add magnesium stearate into Octagonal Blender and Close the lid of Octagonal Blender and mix for 3 minutes at slow speed.

3.9.4 Off load the granules in containers lined with poly bags & record weights.

3.9.5 Intimate QC for Blend sampling.

Item	Qty. (Kg)	Time		Loaded by	Checked By	IPQC Sampling Details		QC A.R.No.
		From	To			Before	After	
TOTAL		**Result: Sample is analysed for Assay and as per Analytical Report No. Compression Stage can be Proceeded.** **Sign/Date IPQA**						

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 3.10 LUBRICATED GRANULES CONTAINERS WEIGHING RECORD

Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				

Note: Store the blend in duly labelled double poly bag inside an airtight HDPE container at temperature NMT 25 ºC and Relative Humidity NMT 55 % until released for compression.

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 3.11 YIELD RECONCILIATION-

Theoretical Batch Size (Kg) (A)	Actual Yield After Lubrication (Kg) (B)	% YIELD = B X 100 A	Limit	Checked By (PROD)	Verified By (QA)

Lubricated Granules are Further Transferred for Compression			
Production Chemist Sign/Date		IPQA Officer Sign/Date	

STEP 3.12 LUBRICATED GRANULES APPROVAL FOR COMPRESSION

3.12.1 QC Report: The Lubricated Granules has been analysed and released for Compression as per the Analytical Report no _____

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP - 4: COMPRESSION

STEP 4.1 Line Clearances - Tablets Compression Area

Equipment ID :			**Capacity (Station) :**		
Line Clearance :					
• Check area ,walls, doors, flowerings is Cleaned Properly and no Traces of previous Product					
• Ensure QC release of Granules before taking for compression.					
• Ensure that compression Machine, dust extractor, dedusting unit is cleaned and arranged properly					
Previous Product	:		Batch No.	:	
Area Cleaning Done By	:		Checked By	:	
Line Clearance Given By QA	:		Date	:	
Line Clearance SOP Ref No	:		Time	:	
Note: Ensure That Temp. Shall NMT 25°C, % RH. Shall NMT 55% during the processing of the materials in Compression area.					

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

4.2 Instruction:

4.2.1 Set up and Operate Compression machine as per SOP .
4.2.2 Compress the blend after due QC approval, Machines-29 Station/51 Station/47 Station
4.2.3 Compress the blend as per the specification and carryout in process checks at specified interval.

PUNCHES AND DIES – CHECK RECORD : For 29 Station/47 Station/51 Station :

Description	Fitted by Operator	Checked by Production
Upper punches		
Lower Punches		
Dies:		

Upper Punches	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
	39	40	41	42	43	44	45	46	47	48	49	50	51						
Upper Punches	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
	39	40	41	42	43	44	45	46	47	48	49	50	51						
Upper Punches	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
	39	40	41	42	43	44	45	46	47	48	49	50	51						

STEP 4.3 COMPRESSION PARAMETERS – Specifications

Parameter & Frequency	Description Every 30 min.	Avg. wt of 20 tablets Every 30 min.	Thickness Every 30 min.	Hardness Every 30 min.	DT Every 120 min.	Friability Every 120 min.
Standard	White, circular flat bevel edged uncoated tablet with break line on one side & other side plain	11.40g ± 5 %	4.1 ± 0.5 mm	NLT 3 Kg/cm2	NMT 15min	NMT 1 % w/w
Limits		10.830 g to 11.970 g	3.6mm to 4.6 mm			

Operator	Cubicle No.	Equip. No.	M/C speed RPM
		PD/EQ/ _____	
Compression Start Date		Compression End Date	

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

Date	Time	Description	Wt.of 20tabs.(gm)		Thickness (mm)		Hardness Kg/cm2		DT.(min)		Friability %		Checked by Production	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	Operator	Officer

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

Date	Time	Description	Wt.of 20tabs.(gm)		Thickness (mm)		Hardness Kg/cm2		DT.(min)		Friability %		Checked by Production	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	Operator	Officer

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

Date	Time	Description	Wt.of 20tabs.(gm)		Thickness (mm)		Hardness Kg/cm2		DT.(min)		Friability %		Checked by Production	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	Operator	Officer

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 4.4 INDIVIDUAL WEIGHT VARIATION RECORD

To be done by Production Supervisor and IPQA officer Alternatively Means Production Chemist will perform checks Initial,08,16 ....and IPQA Officer at 04,12,...so on

Individual wt. variation: 570 mg ± 5% (541.5 mg – 598.5 mg) Frequency: 240 min.

No. of Tablets	Wt. (mg) Date: Time:		Wt. (mg) Date: Time:		Wt. (mg) Date: Time:		Wt. (mg) Date: Time:		Wt. (mg) Date: Time:		Wt. (mg) Date: Time:		Wt. (mg) Date: Time:	
	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1														
Total (T)														
Avg(A)=T /20														
Min Wt.														
Max Wt.														
- %*														
+ %*														
No. of tab above 5%#														
No. of tab below5%#														
Check By														

* + 5% of the average weight. # NMT 2 tablets are more than 5% & none more than 10%.
Calculate as -% = A- Min x 100/A +% = Max- A x 100/A

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 4.5 COMPRESSED TABLETS CONTAINE

RS WEIGHING RECORD

Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

COMPRESSED TABLETS CONTAINERS WEIGHING RECORD

Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				

Total Number of Containers: _____

Total Net weight of the Tablets: _____Kg. = No. of Tablets: _____

INPROCESS YIELD:

Theoretical batch Yield (Kg) A	Weight of Granules Received (B)	No of Tablets to be Compressed (C)	Weight of Tablets After Compression (D)	No of tablets Compressed (E)	Loss during Compression = B- D	Recoverable Tablets	Percentage Yield = D X 100/A

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 4 .6 COMPRESSED TABLETS INSPECTION RECORD

Transfer the tablets to inspection area and inspect the tablets for broken, chipped, black spots and defective tablets on inspection belt or on SS tray using butter paper.

Operation done by: - _____From:- _____ to: - _____

Total tablets taken for inspection (A):- _____ kg.

Total recoverable tablets after inspection (B):- _____ kg.

Total Good tablets after inspection (A-B): _____ kg

% Yield _____ (NLT 98.0 %)

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

4.6.1 WEIGHT OF SORTED TABLETS

Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

WEIGHT OF SORTED TABLETS

Balance ID: **Date:_____**

Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By	Drum No	Gross Wt (Kg)	Tare Wt (Kg)	Net Wt (Kg)	Done By
01					11				
02					12				
03					13				
04					14				
05					15				
06					16				
07					17				
08					18				
09					19				
10					20				

Total Number of Containers: _____

Total Net weight of the Tablets: _____Kg. = No. of Tablets: _____

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

STEP 4.7 COMPRESSED TABLETS SAMPLING DETAILS		
Intimation given by:	Sign/Date: _____	Time: _____
Sampled by (IPQA):	Sign/Date: _____	Time: _____

STEP 4.8 YIELD RECONCILIATION

STAGE	THEORETICAL BATCH SIZE(A)	ACTUAL YIELD (B)	% YIELD = B X 100 A	CHECKED BY (PROD)	VERIFIED BY (QA)

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			

Document checked by:	
Production Chemist:	Quality Assurance:
Sign / Date:	Sign / Date:

STEP 4.9 Destruct Irrecoverable Rejection Tablet by putting in water in presence of QA.

SOP No.:

Destruction supervised done by (Production):	
In presence of QA:	
Sign & Date:	

STEP 4.10 DEVIATION APPROVAL SHEET

DEVIATION	REASON & JUSTIFICATION	PROPOSED BY Production Chemist	APPROVED BY QA

Master BMR Digitally signed by			
	Prepared By	Checked By	Approved by
Name			
User Id			
Date			
Time			