BATCH PRODUCTION AND CONTROL RECORD			
PRODUCT TRIAL BATCH	**PRODUCT CODE**	**EFFECTIVE DATE**	
MFR No. NA	**BMR No.** NA	**BATCH No.**	
REVISION No. **00**	**SUPERSEDE BMR No.** NIL	**PAGE No.** 1 of 25	

BATCH MANUFACTURING RECORD

PRODUCT NAME : TRIAL BATCH FOR ORAL LIQUID
GENERIC NAME :
LABEL CLAIM :

STRENGTH :
MANUFACTURING LICENSE No.:
STANDARD BATCH SIZE :
ACTUAL BATCH SIZE :
PACK SIZE :
MANUFACTURING DATE :
EXPIRY DATE :
SHELF LIFE :
BLOCK / PRODUCTION LINE :
MARKET :
DATE OF COMMENCEMENT :
DATE OF COMPLETION :
BATCH YIELD (%) :
PRODUCT OF (Company Name) :
BMR ISSUED BY (QA) :
DATE :

Note: Engineering Batch BMR

	Prepared By **Executive QA**	**Checked By** **Manager Production**	**Approved By** **Head QA**	**Authorized By** **Head Operations**
Sign				
Date				
Name				

CONTENTS

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 3 of 25	

Specimen Signature record of the persons involved in Manufacturing/Dispensing:

S.No.	Name	E. Code	Designation	Signature

A. DISPENSING:

1. Instructions:

- During Process Check Environmental Conditions to be within Limits (i.e. Temperature NMT 25°C & RH NMT 65%) and Record in Environment Monitoring Record at the time of Start of Dispensing, after Every One Hour and after Every Breakdown (except Raw syrup & preparation area).
- Ensure all equipments are Cleaned and Affixed with "CLEANED" Status Label.
- Ensure that Secondary Gowning of the Dispensing Area and Respective Modules are followed.
- Ensure that all Current Respective SOP's are followed during Dispensing.
- Take Line Clearance from QA before Start of the Dispensing Activity.
- Dispense the Material as per the Bill of Material.
- Take Raw Materials to Dispensing Area and Weight the First Excipients and then Active Ingredients in Double Polyethylene Bags under RLAF.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 5 of 25	

2. OPERATIONAL CHECKS:

Instrument Name	Identification No.	Calibration Status (Ok/Not Ok)	Checked By Sign / Date Warehouse Officer/Executive
Electronic Weighing Balance			
Electronic Weighing Balance			
Electronic Weighing Balance			

3. ENVIRONMENTAL MONITORING: At the time of start of Dispensing, after **Every One Hour** and after Every Breakdown.

Date/ Time	Room No. /Name	Temp. (°C) (Limit NMT 25°C)	% RH (Limit NMT 65 %)	Done By Sign/Date	Checked By Sign/Date	Remarks

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 6 of 25	

4. CALCULATION:

Calculation Done By Production Officer / Executive Sign & Date

Calculation Checked By IPQA Officer / Executive Sign & Date

5. LINE CLEARANCE FOR DISPENSING:

(To Be Performed by Warehouse & Verified by QA persons)

LINE CLEARANCE CHECK LIST – DISPENSING

Previous Product		**Area**	
Batch No.		**Date / Time (Hrs.)**	

S. No.	Check Points	Status (OK / Not OK)	Done By (Warehouse Officer/Exe.)	Checked By (QA Officer/Exec)
1.	Check the **"Status Board"** of the Dispensing Area for following details: Product Name, Batch No., Mfg. Date, Exp. Date, Batch Size and Ensure that the details are matching with the BMR of present batch to be processed			
2.	Check the Cleanliness of the Room and Ensure that it is Free From the Remains of the Previous Batch.			
3.	Check the Cleanliness of the RLAF Unit and ensure that it is Free From the Remains of the Previous Batch.			
4.	Check and Ensure that the RLAF is switched **"ON"** minimum 15 minutes before Start of the Activity and the Pressure Differential across HEPA filter is within limit.			
5.	Check the Temperature and Relative Humidity (RH) of the Dispensing Room (It should be within Specified Range).			
6.	Check the Calibration Status of the Weighing Balance.			
7.	Ensure all Logbooks of the Area (RLAF Usage Log Book, Balance Calibration Log Book, Cleaning Log Book and Environmental Monitoring Log Book etc.) are filled regularly.			
8.	Inspect the Waste Bins and Ensure that it is Free From remains of the Previous Batch			
9.	Check the Availability of On-line BMR			
10.	Check the Approval of Raw Materials from QC by Pasted Approved Labels on Containers.			
11.	Check and Verify the Identity of Raw Materials by Item Code & A.R. No. to be used are as per BMR.			
12.	Check and Ensure the Dispensed Raw Materials are kept in a separate SS Trolley with Proper Status Label.			
13.	Check and Ensure the Liquid Raw Materials are Dispensed in clean SS Container with Proper Status Label. (If Liquid Raw Material is in BOM)			
14.	Ensure Proper Cleaning of Filters of RLAF, Returned Riser and Grill of Filters.			
15.	Check and Ensure the availability of Cleaned Dispensing Tools			
16.	If Line Clearance Not Ok Repeat Line Clearance has to be taken.			

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 8 of 25	

17.	Repeat Line Clearance.			

Note: Write 'NA' where not Applicable

After complete checking as per checklist QA Officer/Executive shall give the Line Clearance of the area by signing on 'Line Clearance Label'.

Checked By Sign / Date _____
(Warehouse Officer/Executive)

Line Clearance Given By Sign / Date_____
(QA Officer/Executive)

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 9 of 25	

AFFIX DISPENSING AREA LINE CLEARANCE LABEL

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 10 of 25	

6. RAW MATERIAL DISPENSING RECORD:

Balance ID No.: Calibration Status (Ok/Not Ok):_____

Balance ID No.: Calibration Status (Ok/Not Ok):_____

S. No.	Material No.	Material Name	Std. Qty. (100 Ltr. Batch Size)	Issued Qty. (For _____ Ltr.)	Unit	A.R. No.	Gross Wt.	Tare Wt.	Net Wt. Issued	Issued By Sign/Date (Warehouse)	Verified By Sign/Date (IPQA)
1.		Carboxy-methyl Cellulose Sodium IP (1260DIACEL)			kg						
2.		Sucrose IP			kg						
3.		Sodium Methyl Paraben IP			kg						
4.		Sodium Propyl Paraben IP			kg						
5.		Col. Sunset Yellow FCF			g						

Raw Material Dispensing Started At (Date/ Time (Hrs.))	Raw Material Dispensing Completed At (Date/ Time(Hrs.))	Dispensed By (Operators) (Sign & Date)	Checked By (Warehouse Officer/Executive) (Sign & Date)	Verified By (QA Officer/Executive) (Sign & Date)

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 11 of 25	

AFFIX THE RAW MATERIALS DISPENSING LABELS

B. MANUFACTURING STAGE:

1. Instructions:

- Read the BMR thoroughly before proceeding with Operation and follow it strictly.
- Carry out all the activities related to Equipment Cleaning and Material Handling strictly as per respective Standard Operating Procedures.
- Label all Equipments and Areas with Status and Product Label and display prominently.
- All Equipment to be used should bear "CLEANED" Equipment Tag and Report of Wash Water analysis releasing the Equipment for use should be made available.
- All Raw Materials Labels, In-process Status Labels, Line Clearance Labels and Equipment Cleaning status labels to be retained with the Batch Production and Control Record.
- Get Line Clearance before beginning of every operation from QA.
- Protective Mask, Hand Gloves and any other Safety Provisions must be followed.
- The persons working in area must follow proper gowning as per the respective SOP.
- Any Deviation from the BMR must be done with prior approval of QA.
- Ensure that all the Raw Material Weights are counter checked before processing.
- Ensure that all the containers containing Raw Material, Intermediate and Final Product Containers are clean before carrying out operations.
- Check the Identification Tags and Weights of the Dispensed Materials and transfer the material to receiving bay of production.
- Following Environmental Conditions are to be observed strictly during Manufacturing Process.
- Use only Purified Water for any addition in this preparation.

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 13 of 25	

2. LINE CLEARANCE FOR MANUFACTURING AREA:

LINE CLEARANCE CHECK LIST – MANUFACTURING AREA

Previous Product		**Batch No.**	
Area		**Date / Time (Hrs.)**	

S. No.	Check Points	Status (OK / Not OK)	Done By Sign/Date (Production)	Checked By Sign/Date (IPQA)
1.	Check the Area is Visually Clean and Free From Dust Particles and ensure that there are no Previous Product Materials/Unwanted Materials.			
2.	Ensure the "**Status Board**" of the area is Neatly and Duly written with **'Batch Details'** as per mentioned in BMR like Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date.			
3.	Check the cleanliness of all Equipments which are used in Manufacturing are done as per Respective Cleaning SOP.			
4.	Ensure that all Equipments which are used in Manufacturing are free from any remains of the Previous Batch / Product material.			
5.	Ensure the Waste Bins are properly Cleaned and Placed in Proper Place.			
6.	Check and Ensure that the Temperature and Relative Humidity of the Area are within the Specified Limit as per mentioned in BMR.			
7.	Check and Ensure that the Machine Log Book, Cleaning Log Book and Environmental Monitoring Log Book are filled correctly.			
8.	Check the proper status labeling on the machines. Ensure that the machine in Cleaning Area has appropriate **Status Label – To Be Cleaned / Cleaned**.			
9.	Check and Ensure that the Wash Water / Swab are released from Quality Control and report attached with BMR before signing as 'Released' on Cleaned label.			
10.	Check and Ensure that the Purified Water Report are attached with BMR.			
11.	Check the Cleaning and Calibration Status of Weighing Balance.			
12.	Check and Verify the Item Code and Weight of Dispensed Raw Material with BMR.			
13.	Check the BMR is filled up to Dispensing Stage.			
14.	If Line Clearance Not Ok Repeat Line Clearance has to be taken.			
15.	Repeat Line Clearance.			

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 14 of 25	

Note: Write 'NA' where Not Applicable.

After complete checking as per checklist QA Officer/Executive shall give the line clearance of the area by signing on 'Line Clearance Label'.

Checked By Sign / Date _____
(Prod. Officer/Executive)

Line Clearance Given By Sign / Date_____
(QA Officer/Executive)

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 15 of 25	

AFFIX MANUFACTURING AREA LINE CLEARANCE LABEL

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 16 of 25	

AFFIX PURIFIED WATER REPORT

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 17 of 25	

3. ENVIRONMENTAL MONITORING: At the time of start/End Manufacturing, after every **4 Hour** and **After Every Breakdown**.

Date/Time	Room No./Name	Temp. (°C) Limit (NMT 25°C)	% RH Limit (NMT 65 %)	Done By Sign/Date (Operator)	Checked By Sign/Date (Production)	Remarks

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 18 of 25	

4. EQUIPMENT DETAILS:

Name of Equipment	Equipment ID No.	Previous Product	Batch No.	Cleanliness (OK/Not OK)	Checked by Sign / Date (Production)	Verified by Sign / Date (IPQA)
Stirrer						
Manufacturing Tank						
In-line Homogenizer						
In line-Colloidal Mill						
Transfer Pump / Lobe Pump						
Holding Tank						
Bulk Transfer Line						
Utensils						
Hose Pipe						
Hose Pipe						
Hose Pipe						
Hose Pipe						

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 19 of 25	

5. VERIFICATION OF DISPENSED RAW MATERIALS

(To Be Performed at Manufacturing Area)

a. Balance ID No.: _____ Calibration Status (Ok/Not Ok):_____

b. Balance ID No.: _____ Calibration Status (Ok/Not Ok):_____

S. No.	Material No.	Material Name	Std. Qty. (For 100 ltr. Batch size)	Issued Qty. (……...ltr.)	A. R. No.	Gross Weight	Units	Checked By Sign/Date (Production)	Verified By Sign/Date (IPQA)
1.		Carboxy-methyl Cellulose Sodium IP (1260DIACEL)					kg		
2.		Sucrose IP					kg		
3.		Sodium Methyl Paraben IP					kg		
4.		Sodium Propyl Paraben IP					kg		
5.		Col. Sunset Yellow FCF					g		

6. PREPARATION OF SYRUP:

VERIFICATION OF DISPENSED RAW MATERIALS: Verify the Weight of Dispensed Raw Material against the Quantity mentioned in the Bill of Raw Materials. Verify the A. R. No. of Dispensed Raw Materials as mentioned in the Bill of Raw Materials.

STEP 1. Primary Syrup Preparation:

a. Take **6 Ltr.** (……Ltr.) of Purified water and warm at 90^0C in SS jacketed tank.

Equipment No.	Process Start Time / Date	Temp. of Purified water	Process Completed Time / Date	Checked By (Sign & Date) (Production)	Verified By (Sign & Date) (QA)

b. Add slowly **10.0 Kg** (……Kg) of Sucrose with continuous stirring at 70-75^0C temperature till clear solution observed.

Equipment No.	Process Start Time / Date	Stirrer Speed	Temp(^{0}C)	Mixing Time		Process Completed Time / Date	Checked By (Sign &Date) (Production)	Verified By (Sign & Date) (QA)
				From	To			

STEP 2. Transfer of Sugar Syrup:

a. Transfer the prepared sugar syrup (**Step 1)** into main manufacturing tank through 200# nylon cloth under continuous stirring.

Equipment No.	Process Start Time / Date	Stirrer Speed	Mixing Time		Process Completed Time / Date	Checked By (Sign &Date) (Production)	Verified By (Sign & Date) (QA)
			From	To			

STEP 3. Preparation of Suspension Base:

a. Add slowly Carboxy Methyl Cellulose Sodium 0.6 kg (……kg) into manufacturing tank with continuous stirring till translucent mass observed.

Equipment No.	Process Start Time / Date	Stirrer Speed	Mixing Time		Process Completed Time / Date	Checked By (Sign &Date) (Production)	Verified By (Sign & Date) (QA)
			From	To			

b. Allow the above solution to stand for 4-5 hours. Cool upto 40-45^{0}C.

Equipment No.	Process Start Time / Date	Temparature after cooling	Process Completed Time / Date	Checked By (Sign &Date) (Production)	Verified By (Sign & Date) (QA)

STEP 4. Addition of Sodium Methyl Paraben & Sodium Propyl Paraben:

a. Dissolve **0.100 Kg** (……Kg) of Sodium Methyl Paraben and 0.020 kg (……Kg) of Sodium Propyl Paraben in 2.0 ltr (…….ltr.) of purified water under stirring till clear solution observed. Filter the solution and transfer into manufacturing tank.

Equipment No.	Process Start Time / Date	Stirrer Speed	Mixing Time		Process Completed Time / Date	Checked By (Sign & Date) (Production)	Verified By (Sign & Date) (QA)
			From	To			

STEP 5. Addition of Colour:

a. Take **0.80 Ltr** (……Ltr) of Purified water into SS Vessel.

b. Dissolve **10.0 gm** (……gm**)** of Col. Sunset Yellow under continue stirring and Transfer the solution into manufacturing tank through 200# nylon cloth.

Equipment No.	Process Start Time / Date	Stirrer Speed	Mixing Time		Process Completed Time / Date	Checked By (Sign & Date) (Production)	Verified By (Sign & Date) (QA)
			From	To			

STEP 6. Volume Adjustment:

a. Allow the bulk to settle for 10 min.

b. Make volume up to **_____Liters** (……..Liters) with Purified Water. **Scale Reading**……

Checked By _____ Verified By_____
(Production) (QA)

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 22 of 25	

Process Start Time / Date	Process Completed Time / Date	Checked By (Sign/ Date) (Production)	Verified By (Sign / Date) (IPQA)

- Label the storage tanks with proper identification w.r.t. Product Name, Batch No. Mfg Date, use before, Batch Size & Status Intimate quality control department to arrange collect the sample for analysis.

7. SAMPLE REQUEST FOR QC ANALYSIS:

a. Send Test Request Form to QA for Sampling.

b. After Sampling, QA shall send the Sample along-with Intimation to QC for Analysis.

Intimation No.	Intimated By Sign / Date / Time (Production)	Intimation Received By Sign / Date / Time (IPQA)	Quantity Sampled	Sampled By Sign / Date / Time (IPQA)

c. After receiving the QC confirmation (report attach) for liquid bulk is Release / Not Release for Filling.

QA Officer/Executive Sign _____ Date _____ Time _____

8. FILTRATION:

a. Filter the Suspension through 60# nylon cloth/SS SIEVE and collect the filtrate solution in Holding Tank.

b. Store the Solution in Holding Tank.

c. When bulk product is not packed within 24 hrs, then Maximum period of storage (Hold Time) is 72 Hrs at NMT 25^0C.

Process Start Time / Date	Integrity of Sieve (OK/Not OK)		Process Completed Time / Date	Process Done By	Checked By (Sign & Date) (Production)	Verified By (Sign & Date) (QA)
	Before	After				

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 23 of 25	

9. BULK SOLUTION RECONCILIATION:

S.No.	Particulars	Results
a.	Actual Batch Size	liters
b.	Batch Quantity Received after Final Filtration	liters
c.	Bulk Sample send to QC for Analysis	liters
d.	Bulk Received for Filling Process	liters
e.	Percentage Yield	$\frac{(c + d) \times 100}{a}$ = _____X 100 = _____%.
Calculation Done By Sign & Date (Production)		**Calculation Checked By Sign & Date (QA)**

BATCH PRODUCTION AND CONTROL RECORD				
PRODUCT TRIAL BATCH	**BATCH No.**	**MFG. DATE**	**EXP. DATE**	
MFR No. NA	**BMR No.** NA	**BATCH SIZE**	**PAGE No.** 24 of 25	

10. IN – PROCESS OBSERVATIONS (To be Filled by QA only):

S. No.	Date / Time	Shift	Observations	Informed To Production (Officer/ Executive)	Observed By IPQA (Officer / Executive)	Action Taken By Production (Officer/ Executive)	Verified By QA (Officer/ Executive)

11. VERIFICATION OF MANUFACTURING STEPS, DOCUMENTS/ DATA & REPORTS:

	Manager Production	Quality Assurance Manager
Name		
Sign & Date		
Emp. Code		

CERTIFICATE FOR BATCH MANUFACTURING:

I, the undersigned, approved technical staff having prescribed qualification & experience, hereby confirm that the above batch is manufactured under my direction & supervision. All process relating to the selection, weighing and measuring of raw material & processing during various stages are performed by trained personnel. All statutory requirements prescribed for manufacturing under Drugs & Cosmetics Act, 1940 & CGMP standards are duly followed.

Competent Technical staff for Mfg (Name): ----------

(Sign): ----------

(Emp. ID): ----------

12. REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated by
00	New Document	NA		