	PHARMA DEVILS PRODUCTION DEPARTMENT	
	BATCH MANUFACTURING RECORD	

Product Code:	**BMR No.:**	
Product Name:	**Generic Name:** Aceclofenac & Paracetamol Oral Suspension	
Document No.:	**Effective Date:**	**Page No.:** 1 of 12
Batch No.:	**Batch Size:**	**Supersedes No.:**

Location:	
Block: Production Liquid (PL)	
Label Claim:	**Each 5 ml contains:** Aceclofenac IP …… 50 mg Paracetamol IP...…… 125 mg In flavored syrupy base…….. q.s. Colour: Tartrazine
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

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1.0 MASTER FORMULA:

BILL OF RAW MATERIALS

S.No.	Ingredients	Spec.	Each 5 ml	Overages in %	Std. Qty. for 1000 Lts. In Kg
1.	Paracetamol	IP	125 mg	-----	25.00#
2.	Aceclofenac Sodium	IP	50 mg	-----	10.00#
3.	Polysorbate-80	IP	-----	-----	2.14
4.	Sucrose	IP	-----	-----	600.00
5.	Sodium Methyl Paraben	IP	-----	-----	2.00
6.	Sodium Propyl Paraben	IP	-----	-----	0.20
7.	Citric Acid	IP	-----	-----	1.075
8.	Xanthum Gum Normal	IP	-----	-----	4.00
9.	Glycerine	IP	-----	-----	14.28
10.	Sorbitol Solution 70 %	IP	-----	-----	57.14
11.	Sodium Citrate	IP	-----	-----	1.43
12.	Sodium Benzoate	IP	-----	-----	1.43
13.	Polyethylene Glycol-400	IP	-----	-----	4.28
14.	Sodium Chloride	IP	-----	-----	1.43
15.	Aerosil	IP	-----	-----	2.38
16.	Sodium Saccharin	IP	-----	-----	1.43
17.	Colour Tartrazine	IH	-----	-----	0.028
18.	Essential Mango Flavour	IH	-----	-----	3.00
19.	Purified Water	IP	QS to 5 ml	-----	QS to 1000 Lts.

Note: * Paracetamol & Aceclofenac Sodium IP adds after calculation if assay is below 99%.

	Prepared By	Checked By	Approved By
Signature			
Date			

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CALCULATION SHEET

1- Paracetamol 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 **Paracetamol IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

Assay on as such basis = (100-LOD) X Assay on dried basis = _____%
100

A.R. No. of **Paracetamol IP**	Assay on as such basis **(A1)**	Actual quantity of this A.R. No to be dispensed =
	----------%	_____# x 100 = ----------Kg A1

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

A.R. No. of **Paracetamol IP**	Assay on as such basis (a1)	Actual quantity Available (b1) (Kg)	Qty. on 100 % assay basis = (b1) x (a1) ---------- = _____ Kg 100	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) = (e1) x 100 =----------Kg
(f1)

Therefore total quantity of **Paracetamol 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			

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CALCULATION SHEET

2- Aceclofenac Sodium 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 **Aceclofenac Sodium IP** is to be used:
If calculated quantity is less than std. qty. then dispense std. Qty.

Assay on as such basis = (100-LOD) X Assay on dried basis = _____%
100

A.R. No. of **Aceclofenac Sodium IP**	Assay on as such basis **(A1)**	Actual quantity of this A.R. No. to be dispensed =
	----------%	_____# x 100 = ----------Kg A1

PART B: To be Calculated when more than one A.R. No's of **Aceclofenac Sodium IP** is to be used:

A.R. No. of **Aceclofenac Sodium IP**	Assay on as such basis (a1)	Actual quantity Available (b1) (Kg)	Qty. on 100 % assay basis = (b1) x (a1) ---------- kg 100	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) = (e1) x 100 =----------Kg
(f1)

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

Assay calculation:

Sign/ Date		
Department	**Done By (Production)**	**Checked By (QA)**

	Prepared By	Checked By	Approved By
Signature			
Date			

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2.0 LINE CLEARANCE OF DISPENSING:

Dispensing of Raw Materials (SOP No. :_____)

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

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

S.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……..(6-10 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.	

Differential pressure across RLAF and Room:_____ (Limit: Between 5 to 15 Pascal)

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

Note:

1. Use nose masks and gloves during dispensing operation.
2. Dispensing operation should be carried out by stores and counter checked by Production Supervisor and QA.
3. Check the temperature and relative humidity of the area before commencing the dispensing.
4. Check before dispensing all raw materials approved by QC dept.
5. Properly check A.R. No. /Materials Name/ Item Code No. / Expiry Date etc.

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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

S. No.	Ingredients	Std. Qty. for 1000 Lts. In Kg	@Req. Qty. in Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. by Store	Checked By	
						Gross	Tare	Net		Prod.	QA
1.	Paracetamol IP	25.00#									
2.	Aceclofenac Sodium IP	10.00#									
3.	Polysorbate-80 IP	2.14									
4.	Sucrose IP	600.0									
5.	Sodium Methyl Paraben IP	2.00									
6.	Sodium Propyl Paraben IP	0.20									
7.	Citric Acid IP	1.075									
8.	Xanthum Gum Normal IP	4.00									
9.	Glycerine IP	14.28									
10.	Sorbitol Solution 70 % IP	57.14									
11.	Sodium Citrate IP	1.43									
12.	Sodium Benzoate IP	1.43									
13.	Polyethylene Glycol-400 IP	4.28									
14.	Sodium Chloride IP	1.43									
15.	Aerosil IP	2.38									
16	Sodium Saccharine IP	1.43									
17.	Colour Tartrazine IH	0.028									
18.	Essential Mango Flavour IH	3.00									
19.	Purified Water IP	QS to 1000 Lts.									

Note: # Paracetamol & Aceclofenac Sodium 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:
Quality Assurance
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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

S. No.	Ingredients	Std. Qty. for 1000 Lts. In Kg	@Req. Qty. in Kg	Issued Qty. in Kg	A.R. No.	Weight in Kg			Wt. by Store	Checked By	
						Gross	Tare	Net		Prod.	QA
1.	Paracetamol IP	25.00#									
2.	Aceclofenac Sodium IP	10.00#									
3.	Polysorbate-80 IP	2.14									
4.	Sucrose IP	600.0									
5.	Sodium Methyl Paraben IP	2.00									
6.	Sodium Propyl Paraben IP	0.20									
7.	Citric Acid IP	1.075									
8.	Xanthum Gum Normal IP	4.00									
9.	Glycerine IP	14.28									
10.	Sorbitol Solution 70 % IP	57.14									
11.	Sodium Citrate IP	1.43									
12.	Sodium Benzoate IP	1.43									
13.	Polyethylene Glycol-400 IP	4.28									
14.	Sodium Chloride IP	1.43									
15.	Aerosil IP	2.38									
16	Sodium Saccharine IP	1.43									
17.	Colour Tartrazine IH	0.028									
18.	Essential Mango Flavour IH	3.00									
19.	Purified Water IP	QS to 1000 Lts.									

Note: # Paracetamol & Aceclofenac Sodium 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:
Quality Assurance
Date

	Prepared By	Checked By	Approved By
Signature			
Date			

BATCH MANUFACTURING RECORD

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3. LINE CLEARENCE:

CLEANING AND WASHING RECORD OF MANUFACTURING SECTION

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

Cleaned On : _____ Cleaned By: _____

Area/ Equipment	Identification No.	Cleaned as per SOP	Cleaned by	Checked By Prod.	Verified by QA
Sugar Preparation Vessels					
Mfg. Vessels					
Storage Vessels					
SS Container					
Solvent Transfer Pump					
Filter Press					
Jacketed vessel 500 Lts.					
Basket Filter					
Colloidal Mill					
Inline homogenizer					

Rinse equipment's with fresh purified water.

In case of product change over send final wash water sample of equipment to Q.C.D. for product line clearance.

Caution:

1. All equipment's and accessories must be cleaned as per SOP.
2. All operations/cleaning procedures should be as per existing SOP for suspension.
3. Use gloves and nose masks while manufacturing of the drug product.
4. Carry out all manufacturing activities under control condition.
5. Active materials opened must be utilized fully.
6. Stirring should be gentle during manufacturing process.

	Prepared By	Checked By	Approved By
Signature			
Date			

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LINE CLEAREANCE CHECK LIST FOR MANUFACTURING AREA

Product Name: _____ **Batch No.:** _____

Time : _____ **Date :** _____

Previous Product: _____ **Batch No.:** _____

S. No.	Check Points	Observation	Checked By Prod.	Verified By QA
1.	Check and ensure that the area is clean and free of previous batch materials.			
2.	Check and ensure that the tank is clean and free of previous batch materials.			
3.	Check and ensure that the temperature of the area is maintained.			
4.	Check and ensure that the dipstick is clean and free of previous batch materials.			
5.	Check and ensure that the sieve is clean and free of previous batch materials. Check the integrity of sieve.			
6.	Check and ensure that the scoops/spoon and secondary vessel is clean and free of previous batch materials.			
7.	Check and ensure that the display board is clean.			
8.	Ensure that the area is maintained for taking next batch.			
9.	Check that the BMR of the next batch is issued accordingly.			
10.	Check that the batch is dispensed according to the BMR.			

Remarks: Write "OK" if found satisfactory, "Not OK" in case of not satisfactory and "NA" if not applicable.

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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MANUFACTURING PROCESS

Precautions:

1. Use only stainless steel equipment in manufacturing.
2. Subdivide as soon as possible after bulk manufacturing.
3. Check cleanliness of all containers, pumps tubing, etc. prior to use.
4. Rinse all containers with appropriate quantity of purified water after transfer of solution.
5. Check sieve integrity initial and final after every addition.

A.R. No. of Purified Water: _____ pH of Purified Water: _____

Step	Date	Process	Qty.	Time		Operator	Ckd. By	
				From	To		Prod.	QA
1		**Base Preparation:** Take required qty. of **Purified Water** in a suitable capacity of S.S. jacketed vessel and heat the purified water up to 80 to 90^{0}C.						
2.		**Addition of Preservative-** In another SS container take required qty. of purified water add and dissolve one by one the following raw materials- **Sodium Methyl Paraben** (_____ Kg), **Sodium Propyl Paraben** (_____ Kg) and **Sodium Benzoate** (_____ Kg). Check the clarity after addition of the materials and then transfer it to the Step-1.						
3.		In Step-1add **Sucrose (**_____ Kg) to the hot purified water under continuous stirring and maintain temp. 80^{0}C for 30 minutes under constant stirring. Check the clarity after addition of the materials.						
4.		**Cooling of Sugar Syrup-** Apply cooling and cool the sugar up to 40-45^{0}C. Filter the Sugar Syrup through 200# muslin cloth and collect in manufacturing tank						
5.		Then add under continuous stirring **Polyethylene Glycol-400** (_____Kg) in the main manufacturing vessel.						
6.		**Soaking of Paracetamol-** In another SS Container take required qty. of **Sorbitol 70%** (____Kg) add **Paracetamol** (____# Kg) and soak for 4 to 5 Hrs.						

	Prepared By	Checked By	Approved By
Signature			
Date			

PHARMA DEVILS

PRODUCTION DEPARTMENT

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Step	Date	Process	Qty.	Time		Operator	Ckd. By	
				From	To		Prod.	QA
7.		**Soaking of Xanthum Gum & Aerosil -** In SS Container take required qty. of hot purified water add in it **Xanthum Gum** (____Kg) and **Aerosil** (____ Kg) under manual stirring and soak it for 3-4 Hrs.						
8.		**Soaking of Aceclofenac-** In another SS Container take required qty. of **Glycerine** (____Kg) add **Aceclofenac** (____# Kg) mix and soak for few Hrs.						
9.		In another SS Container take required qty. of purified water add and dissolve one by one the following raw materials- **Sodium Chloride** (____Kg) and **Sodium Citrate** (_____Kg) Check the clarity after addition of the materials and then transfer it to the main manufacturing tank under continuous stirring.						
10.		In SS Container take required qty. of purified water add and mix **Sodium Saccharine** (_____ Kg) then transfer it to the main manufacturing tank under continuous stirring.						
11.		**Addition of soaked Xantham Gum-** Transfer milled soaked **Xantham Gum** (_____#Kg) to the main manufacturing tank under continuous stirring.						
12.		Check the **pH** of the bulk. Range: 5.5 to 6.0 Citric acid used for pH adjustment.						
13.		**Addition of soaked Paracetamol-** Transfer milled soaked **Paracetamol** (_____#Kg) to the main manufacturing tank under continuous stirring.						
14.		**Addition of soaked Aceclofenac -** Transfer milled soaked **Aceclofenac** (_____#Kg) to the main manufacturing tank under continuous stirring.						
15.		In separate SS vessel take sufficient amount of purified water and dissolve **Colour Tartrazine (**____Kg). Check the clarity after addition of the materials and then transfer it to the main manufacturing vessel.						

	Prepared By	Checked By	Approved By
Signature			
Date			

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Step	Date	Process	Qty.	Time		Operator	Ckd. By	
				From	To		Prod.	QA
16.		Under continuous stirring add **Polysorbate-80 (____** Kg) in the main manufacturing vessel.						
17.		Add **Ess. Mango Flavour** (____liters) (Temp. below 40^0C) to the main manufacturing vessel under continuous stirring.						
18.		Check pH, it should be between **pH 5.5 to 6.0,** if pH is at higher side add Citric acid solution to adjust the pH. **Actual pH**_____						
19.		Make up the volume with Purified Water and stir for 10-15 minutes. Filter of bulk suspension by using 60# nylon cloth.						

Intimate IPQA to withdraw sample from the bulk storage tank for analysis as per the specification.
After getting the approval from IPQA transfer the material for filling.

4.0 YIELD RECONCILIATION:

Bulk Yield: Limit NLT 100.0 %

Theoretical volume: As per required batch size.

Actual Volume _____ Liters. _____ % yield.

Volume Checked by: _____ Date: _____ Sign: _____

Sampled Qty.:_____ Sampled by: _____ 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. Manager)

6.0 ANY DEVIATION:

Deviation No.	Reason for deviation

7.0 HISTORY SHEET:

BMR No.	New BMR No.	Revision No.	Reason For Revision
	-----	00	New BMR

	Prepared By	Checked By	Approved By
Signature			
Date			