



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## BATCH MANUFACTURING RECORD

<b>Product Code:</b>		<b>BMR No.:</b>	
<b>Product Name:</b> Aceclofenac (Sustained Release) & Rabepazole Sodium Capsules		<b>Generic Name:</b> Aceclofenac (Sustained Release) & Rabepazole Sodium Capsules	
<b>Document No.:</b>	<b>Effective Date:</b>	<b>Page No.:</b> 1 of 14	
<b>Batch No.:</b>	<b>Batch Size:</b>	<b>Supersedes No.:</b>	

<b>Location:</b>	
<b>Block:</b> Production Capsules (PC)	
<b>Label Claim:</b>	<p>Each hard gelatin capsule contains:</p> <p>Aceclofenac IP..... 200 mg (In sustained release pellets)</p> <p>Rabepazole Sodium IP..... 20 mg (As enteric coated pellets )</p> <p>Excipients ..... q.s.</p> <p>Approved color used in empty gelatin shells and pellets.</p>
<b>Mfg. Lic. No.:</b>	
<b>Product Lic. No.:</b>	NA
<b>Self-Life:</b>	24 Months
<b>MFR No.:</b>	
<b>Mfg. Date:</b>	
<b>Exp. Date:</b>	
<b>BMR Issued No.:</b>	
<b>Party:</b>	

<b>Issued By Stamp &amp; Sign.</b>

Responsibility	Name	Designation	Sign	Date
<b>Prepared By</b>				
<b>Checked By</b>				
<b>Approved By</b>				



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**1.0 MASTER FORMULA:**

**BILL OF RAW MATERIALS**

S.No.	Ingredients	Spec.	Qty. in mg Per Capsule	Overages %	Std. Qty. for 1 Lac. in Kg
1.	Aceclofenac (SR) & Rabepazole Sodium (EC) Mixed pallets	IP	470 mg eq. to 200 & 20 mg	----	47.00
2.	Capsule Size: "0" Colour: Red/Red	-----	95.50 mg	-----	100100 Nos.
<b>Filled weight of capsule</b>			565.50 mg		

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Signature</b>			
<b>Date</b>			



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**2.0 GENERAL INSTRUCTIONS:**

- Current version of SOPs should be referred during operation.
- Dispensed raw material/bulk blend/ Capsule filling 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 filled within 15 days.
- The filled capsule 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.

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. ----- °C (NMT 27°C), RH-----% (NMT 55.0%), DP.....(6 to10 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.	

<b>Previous product name:</b>		<b>Batch No.:</b>	
<b>Differential pressure across RLAF and Room:</b>		(Limit(Between 5 to 15 Pascal))	
<b>Checked By (Production):</b> <b>Sign &amp; Date:</b>		<b>Verified By (IPQA):</b> <b>Sign &amp; Date:</b>	

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Signature</b>			
<b>Date</b>			



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<b>Batch No.:</b>	<b>Batch Size:</b>	<b>Supersedes No.:</b>	

### 2.2 BILL OF RAW MATERIALS:

(PRODUCTION COPY)

S. 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	Ckd. By	
						Gross	Tare	Net		Prod.	QA
1.	Aceclofenac (SR) & Rabeprazole Sodium (EC) Mixed pallets	47.00									
2.	Capsule Size: "0" Colour: Red/Red	100100 Nos.									

**Note:** @ 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			



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<b>Batch No.:</b>	<b>Batch Size:</b>	<b>Supersedes No.:</b>	

Page No. 5 of 14 store copy

### BILL OF RAW MATERIALS

(STORE COPY)

S. 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
1.	Aceclofenac (SR) & Rabepazole Sodium (EC) Mixed pallets	47.00									
2.	Capsule Size: "0" Colour: Red/Red	100100 Nos.									

**Note:** @ 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			



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### 3.0 WEIGHING OF FINAL BLEND:

Date: .....

Container No.	Gross weight	Tare weight	Net weight	Weighed by	Checked by
1/					
2/					
3/					
4/					
5/					
6/					
7/					
8/					
9/					
10/					
11/					
<b>Total</b>					

**Done by Production**  
Sign / Date:

**Verified by IPQA**  
Sign/ Date:

	Prepared By	Checked By	Approved By
<b>Signature</b>			
<b>Date</b>			



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#### 4.0 CAPSULES FILLING:

**Date:** \_\_\_\_\_

**Started at:** \_\_\_\_\_

#### 4.1 Line clearance:

**Previous product:** \_\_\_\_\_, **Batch No.:** \_\_\_\_\_

S. 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 capsule filling 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 =.....°C (NMT 27°C), 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:

S.No.	Capsule Filling Instruction	Observations	Checked (Production)	Verified By (IPQA)
1.	Collect the approved granules from the granules store for filling.			
2.	Ensure the correct set is assembled in the capsule filling machine.			
3.	Ensure the availability and online filling of Batch Document.			
4.	Collect the capsules from the discharge chute and check them individually for any damages on the surface before continuing the operation of filling machine.			
5.	If filling of capsules 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 filled capsules 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			

	Prepared By	Checked By	Approved By
<b>Signature</b>			
<b>Date</b>			



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<b>Batch No.:</b>	<b>Batch Size:</b>	<b>Supersedes No.:</b>	

### 4.3 IN PROCESS CHECKS:

#### 4.3.1 Specification:

S.No.	Parameters	Requirement	Frequency of Monitoring
1.0	Description	Red/Red color body/cap & size "0" hard gelatin capsule containing brown & white color spherical pellets.	At the start of machine
2.0	Wt. of 20 capsules	11.31 gm $\pm$ 3%	Every 30 Minutes
3.0	Avg. weight	565.50 mg $\pm$ 5%	Every 2 Hours
4.0	Average fill weight	470 mg $\pm$ 5%	Every 2 Hours
5.0	Uniformity weight	565.5 mg $\pm$ 5%	Every 2 Hours
6.0	Lock length	21.5 $\pm$ 0.5 mm	Every 2 Hours
7.0	DT	NMT 30 min	Every 2 Hours
8.0	Appearance	Red/Red colour body/cap and size "0" capsules	Every 2 Hours
9.0	Temperature	NMT 27°C	Every 2 Hours
10.0	RH	NMT 55%	Every 2 Hours

	Prepared By	Checked By	Approved By
<b>Signature</b>			
<b>Date</b>			





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**4.4 In-process observation sheet for production:**

Description:										
Date										
Time										
Wt. of 20 Caps. 11.31 gm $\pm$ 3%										
Average weight 565.50 mg $\pm$ 5%										
Lock length 21.5 $\pm$ 0.5 mm										
DT NMT 30 min										
Appearance Red/Red color body/cap size "0", hard gelatin cap. containing brown and white colour spherical pallets										
Temperature (NMT 27°C)										
RH (NMT 55%)										
Done By										

Attached additional sheet if required...

	Prepared By	Checked By	Approved By
Signature			
Date			



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<b>Batch No.:</b>			<b>Batch Size:</b>			<b>Supersedes No.:</b>		

### WEIGHT VARIATION OF 20 CAPSULES

Date:															
Time:															
Weight	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.
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3.															
4.															
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12.															
13.															
14.															
15.															
16.															
17.															
18.															
19.															
20.															
Avg. Wt.															
Min wt.															
Max wt.															
Ckd. by															

Note: Frequency every 2 hrs.

Attached additional sheet if required.....

	<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Signature</b>			
<b>Date</b>			



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### 4.5 In-process observation sheet for IPQA:

Description:										
Date										
Time										
Wt. of 20 Caps. 11.31 gm $\pm$ 3%										
Average weight 565.50 mg $\pm$ 5%										
Lock length 21.5 $\pm$ 0.5 mm										
DT NMT 30 min										
Appearance Red/Red color body/cap size "0", hard gelatin cap. containing brown and white color spherical pallets										
Temperature (NMT 27°C)										
RH (NMT 55%)										
Done By										

Attached additional sheet if required...

	Prepared By	Checked By	Approved By
Signature			
Date			



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<b>Batch No.:</b>		<b>Batch Size:</b>		<b>Supersedes No.:</b>	

### WEIGHT VARIATION OF 20 CAPSULES

Date:															
	Time:														
Weight	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.	Empty Shell Wt.	Filled Wt.	Total Wt.
1.															
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18.															
19.															
20.															
Avg. Wt.															
Min wt.															
Max wt.															
Ckd. by															

Note: Frequency every 2 hrs.

Attached additional sheet if required.....

	Prepared By	Checked By	Approved By
Signature			
Date			



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### 4.6 FILLED CAPSULES 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 filled Capsules:** \_\_\_\_\_

**Checked By (Sign & Date):** \_\_\_\_\_

### 4.7 VISUAL INSPECTION OF CAPSULES:

Date: \_\_\_\_\_

Time Duration		Quantity rejected	Done by
From	To		

Total weight of rejected capsules: \_\_\_\_\_ Good capsules weight: \_\_\_\_\_

% Yield: \_\_\_\_\_

**Checked by (Production):** \_\_\_\_\_, **Verified by (IPQA):** \_\_\_\_\_  
(Sign & Date) (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 capsule filling 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.

	Prepared By	Checked By	Approved By
<b>Signature</b>			
<b>Date</b>			



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### 4.8 YIELD RECONCILIATION:

• Average filled weight of capsule (A)=:	mg
• Total weight of filled capsules (B) =	Kg.
•	B
Quantity of filled capsules in Number (C)=-----X 1000 X1000 =	A
• Samples (D)=	
• $\frac{C + D}{\text{Actual batch size}} \times 100 =$	(Yield NLT: 98.50%)

<b>Checked By (Production):</b>	<b>Verified By (IPQA):</b>
---------------------------------	----------------------------

Loss Qty.: \_\_\_\_\_ Kg.

### 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			