Batch Record (Manufacturing and Packing)

Product Name	Cefixime Tablets USP 400 mg		
Label Claim	For Export : Each film coated tablet contains Cefixime USP (as trihydrate) equivalent to Anhydrous Cefixime 400 mg. For Domestic : Each film coated tablet contains Cefixime IP (as trihydrate) equivalent to Anhydrous Cefixime 400 mg.		
Applicable To	Export Market : CEFROM 400 mg Coated Tablet Domestic Market : Cefixime Tablets IP 400 mg		
MFR Reference No.	MFR 421 0823 V01		
BMR Reference No.	BMR 421 0823 V01	BMR Effective Date	4.8.2023
Supercedes BMR No.	None		
Reason for change	New BMR		
Batch Size	25000 Tablets		
Theoretical Core Weight	25 Kg		
This document contains	Batch Record (Manufacturing)		Page No 1 - 41
	Batch Record (Packaging Plan)		Page No 1 - 1
	Batch Record (Packaging)		Page No 1 - 15
	Batch Record (Release)		Page No 1 - 1
	Batch Record (Blend In process Analysis Record)		Page No 1 - 1

Issuance Details	
Batch Number	ELEAF24003
Manufacturing date	FEB 2024
Expiry Date [Shelf Life 36 Months]	January 2027
BMR Issue Date	February 24, 2024
BMR Issue Number	240208

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Batch Summary Sheet

Batch Manufacturing Completed Date : _____02.03.2021_____

Yield Summary	Date	Weight in Kg	% Yield	Yield range	Sign
After Blending	26.02.2021	24.90	99.60	96 – 100 %	✓
After Compression	28.02.2021	24.62	98.48	95 – 100 %	✓
After Coating	02.03.2021	23.00	97.44	95 – 100 %	✓

Batch Packing Completed Date : _____05.03.2021_____

Details of Finished Pack			
Packing Completed Date	05.03.2021		
GPA No./ Date	4931 / 05.02.2021		
GPA quantity	23500		
Analytical sample	90		
Control sample	180		
Observation sample			
Party sample			
Stability sample			
Total Quantity packed	23500		
% Yield [95 – 100 %]	95.28%		
Sign.	VS		
Analytical Report No.	6250440005		
Analytical Report Date	12.03.2021		
Sign.	GSK		
Date of Dispatch	17.03.2021	26.03.2021	
EGP Number	DE/28/147	DE/28/154	
Quantity Dispatched	1005X10T	1350XIOT	

Remark if any :

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

General Instructions

- Wear Hand Gloves and Mask , while handling materials / batch ingredients
- Check Area and Equipment cleanliness before operation
- Check Environmental conditions before and during operation
- Follow line clearance Instructions
- Report any deviation from the procedure to Head of the Department / QA Department

Manufacturing Process Flowchart

Dispensing
Sifting
Blending
Compression with Metal Detection
Coating
Tablet Inspection
Primary Packing
Secondary Packing
Finished Goods

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

In Process Quality Control stages :

Stage	Quantity to be sampled	Test to be performed	Specification	Observation	Inference
Blend	50 gm	Refer Annexure 1	Refer Annexure 1	Refer Annexure 1	Complies / Not complies
Blend Manufacturing Completed on Date : 25/02/24 Sign (Production) :QAB			Blend Released / Not Released for Compression Date : 26/02/24 Sign (Quality Control) :SD		

Stage	Quantity to be sampled	Test to be performed	Specification	Observation	Inference
Compressed Tablets	Refer IPQC Compression Parameter Record	Refer IPQC Compression Parameter Record	Refer IPQC Compression Parameter Record	Refer IPQC Compression Parameter Record	Complies / Not Complies
Compression Completed on Date :27/02/24 Sign (Production) : QAB			Compressed Tablets Released / Not Released for Coating Date : 27/02/24 Sign (Quality Control) :SD		

Stage	Quantity to be sampled	Test to be performed	Specification	Observation	Inference
Coated Tablets	Refer IPQC Coated Tablets Parameter Record	Refer IPQC Coated Tablets Parameter Record	Refer IPQC Coated Tablets Parameter Record	Refer IPQC Coated Tablets Parameter Record	Complies / Not Complies
Coating Completed on Date : 01/03/24 Sign (Production) : QAB			Coated Tablets Released / Not Released for Packing Date :01/03/24 Sign (Quality Control) :SD		

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Instructions cum Checklist for Line Clearance of Dispensing Area / Activity

Dispensing activity to be carried as per SOP No: SOP/STD/002

Sr. No	Instructions	Observation
1	All materials pertaining to previous product removed	yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

Equipment Name	Equipment ID	Operating Range of Balance	Calibration status of Balance	Checked By	Verified By
Balance			Done	PAB	TS
Balance			Done	PAB	TS
Laminar Air Flow				PAB	TS

Line Clearance record

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
	Cefixime			YJ	24/02/2024

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Bill of Material

Core Material

Std Qty per tablet in mg	Ingredient	Spec	Std Qty / batch [Kg]
447.66*	Cefixime Trihydrate	USP	11.19
416.34#	Microcrystalline Cellulose PH 102	BP	10.41
100	Anhydrous Lactose	USP NF	2.50
24	Croscarmellose Sodium	USP NF	0.60
12	Magnesium Stearate	BP	0.30
1000	Total		25.00

*Standard quantity of Cefixime Trihydrate i.e 447.66 mg per tablet is calculated based on Purity of 89.353 % (Molecular Weight of Cefixime : 453.46) (Molecular Weight of Cefixime Trihydrate : 507.50)

(400 * 100 /89.353) = 447.66 mg

Coating Material

Std Qty per tablet in mg	Ingredient	Spec	Std Qty / batch [Kg]
16	Hypromellose 2910 5mPa.s	BP	0.40
8	Titanium Dioxide	BP	0.20
2	Lake of Sunset yellow	IH	0.05
4	Talc	BP	0.10
$	Purified Water	BP	6.00

$ Does not appear in final product

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Determination of quantity of Active Raw Material and Microcrystalline Cellulose to be dispensed:

Details of Active Raw Material Retest Due Date of Material to be dispensed : __17/07/2024_____		
Manufacturer	Batch No	AR No
	CFx2401013	99A16260
Assay of Cefixime in % on anhydrous basis	Water Content in %	Purity of Cefixime in %
99.1	10.71	88.48
Purity of Cefixime in % = [(100 – water content in %) * Assay in %] ÷100		

Quantity of Cefixime Trihydrate to be dispensed per batch

(89.353 ÷ Actual Purity) * 11.19

Quantity of Microcrystalline Cellulose to be dispensed

21.60 Kg – Quantity of Cefixime Trihydrate dispensed.

#Quantity of Microcrystalline cellulose is compensated according to the quantity of Cefixime trihydrate so as to maintain net weight per compressed tablet of 1000 mg. i.e.

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Dispensing of Active Raw Material

Item Details	AR No	Tare Weight	Net Weight	Gross Weight	Dispensed By	Checked By
Cefixime Trihydrate USP Standard Quantity per Tablet : 447.66 mg Quantity for batch: **___11.30___ Kg**	99A16260	2.53	11.30	13.83	PAD DVT	TS YJ
Microcrystalline Cellulose PH 102 BP Standard Quantity per Tablet : 416.34 mg Determined Quantity for batch in Kg : 10.30	99A16074	2.42	10.30	11.72	PAD DVT	TS YJ
Anhydrous Lactose USP NF Standard Quantity per Tablet : 100 mg Standard Quantity per batch : **2.5 Kg**	99A16148	0.080	2.500	1.580	PAD DVT	TS YJ

Above Material Received By (Production)____QAB_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Raw Material Dispensing

Item Details	AR No	Tare Weight	Net Weight	Gross Weight	Dispensed By	Checked By
Croscarmellose Sodium USP NF Standard Quantity per Tablet : 24 mg Standard Quantity per batch : **0.6 Kg**	99A16207	0.030	0.600	0.630	PAB DVT	TS YJ
Magnesium Stearate BP Standard Quantity per Tablet : 12 mg Standard Quantity per batch: **300 gm**	99A16963	16.4	300	3164	PAB DVT	TS YJ

Above Material Received By (Production)____QAB_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Expiry Date Verification

The shelf life of the product is 36 Months		
Manufacturing Date is	FEB 2024	
Expiry Date [36 months from Manufacturing date is]	JAN 2027	Sign and Date :GSK 24.2.24 Quality Assurance Personnel

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Instructions cum Checklist for Line Clearance of Granulation Area / Activity

Sr. No	Instructions	Observation
1	All materials pertaining to previous product removed	yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

List of Equipment required			
Equipment Name	Equipment ID	Checked By	Verified By
Sifter	MX011	AN	QAB
Planetary Mixer/Bowl	MX014/MX025	AN	QAB
Balance	MX302, MX306, MX022	AN	QAB

Line Clearance record

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
M5	**Cefixime Tablets USP 400 mg**	ELEAF24002	GSK	SKS	25.2.24

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Sieve / Screen Integrity Check Record

Sieve / Screen Description	Sieve ID /Screen ID	Integrity Before Use	Checked By	Integrity After Use	Checked By
20 #	06	OK		OK	
80 #	19	OK		OK	

Temperature – Relative Humidity (% RH) / Pressure Differential Record of Manufacturing room – Every 1 hours

Temperature	Relative Humidity (%RH)	Pressure Differential
NMT 25° C	NMT 50 % RH	NLT 0.6 mm of water

Date	25/02/24	25/02/24				
Time	1.30	2.35				
Temperature	20.7	21.3				
% RH	43.8	40.2				
Pressure Differential						
MG	1.2					
MG	1.0					
MG	1.2					
MG	1.0					
MG						
MG						
Sign	QAB	QAB				

MG : Magnehelic guage

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Dry Mixing

Date of Commencement_____25.02.24_____

I	Activity	Standard / Recommended	Observation / Actual	Time (From – To)	Done By	Checked By
1	Weight Checking of Dispensed Material	Weight Checking	Done	1.35-1.40	KNJ VMS	QAB
2	Sifting : Cefixime Trihydrate _11.30_Kg	20 #	20#	1.35-1.40	KNJ VMS	QAB
3	Simultaneous Sifting: Microcrystalline Cellulose 10.30 Kg Anhydrous Lactose 2.5 Kg Croscarmellose Sodium 0.6 Kg	20 #	20#	1.35-1.40	KNJ VMS	QAB
4	Simultaneous Sifting : Material sifted at step 2 and 3 and load in PLM bowl	20 #	20#	1.35-1.40	KNJ VMS	QAB
5	Blending : Material in PLM bowl at step 4	Slow speed 25 minutes	20#	1.35-1.40	KNJ VMS	QAB
6	Sifting Magnesium Stearate 300 gm	80 #	20#	1.35-1.40	KNJ VMS	QAB
7	To material sifted at step 6, add @ 1 – 2 Kg of material in PLM bowl after step 5. Mix well in polybag and load uniformly in PLM bowl		20#	1.35-1.40	KNJ VMS	QAB

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

I	Activity	Standard / Recommended	Observation / Actual	Time (From – To)	Done By	Checked By
8	Lubrication : Material in PLM bowl after step 7	Slow Speed 3 minutes	Slow speed 3min	2.45-2.45	KNJ VMS	QAB
9	Unload the blend in LDPE polybags and these polybags are to be placed in HDPE drums with lid. Label the drums with details of Product Name , Batch No , Mfg Date , Exp Date , Weight of each drum and Stage of material.		Done	2.48-2.53	KNJ VMS	QAB

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Blending Stage yield

Drum No	1	2			Total
Gross Weight [Kg]	27.51				27.51
Tare Weight [Kg]	2.60				2.60
Net Weight [Kg]	24.91				24.91

Good Yield	Theoretical	Expected	Actual
Weight [Kg]	25	24.00 – 25.00	24.91
Yield [%]	100 %	96 to 100 %	99.61

Granulation Activity Yield Accountability	-	As a % of batch size
Issued Batch size (in Kg)	25	100
Good Yield of blend (in Kg)	24.91	99.64
Sample quantity (in Kg)	.05	0.20
Non-usable material (collected and destroyed) (in Kg)	.02	0.08
Unaccountable Loss in % (NMT 0.5 % w/w of batch size)	-	0.08

Date of Completion ____25.02.24_____ Assigned Hold Time [50 days] Validity _____14.04.24_____

Checked By _____QAB_____
[Production]

Blend Released / Not Released for Compression : Sign [Quality Control] ____SD____

Next stage activity started on ____27.02.24_____ Checked By ___QAB__[Production]

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Instructions cum Checklist for Line Clearance of Compression Area / Activity

Sr. No	Instructions	Observation
1	All materials pertaining to previous product removed	yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

Name of machineries required			
Equipment Name	Equipment ID	Checked by	Verified By
23 station single rotary compression machine	MX041	AN	QAB
Metal Detector cum Dedustor	MX196	AN	QAB
Dust collector	MX049	AN	QAB
Punch set	47U,46LD	AN	QAB
Balance	MX044 , MX050 , MX243	AN	QAB

Line Clearance record

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
M7	**Cefixime Tablets USP 400 mg**	ELEAF24002	AN	SKS	

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Compression activity done / performed by: N52

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Compression

Date of Commencement____27.02.24_____

Description of compressed tablets	White to off white colored capsule shaped, uncoated tablet with breakline on one side and plain on other side

Punch Details	
Size	18.5 × 8.5 mm
Shape	Capsule shape
Upper	Breakline
Lower	Plain

Environmental Conditions to be maintained during compression	
Temp	NMT 25° C
Relative Humidity (% RH)	NMT 50 % RH

Parameters	Specification
Intended Weight per tab.(mg)	1000
Limit for weight of Ind. Tablet ± 5 % (mg)	950 – 1000 – 1050
Weight per 30 Tabs ± 2 % (gm)	29.40 – 30.00 - 30.60
Hardness (Kg / cm^2)	Between 10 - 20
Thickness (mm)	6.3 – 6.9
Friability (% w/w)	NMT 1
Disintegration Time (minutes)	NMT 15
Machine Speed in rpm	18 – 22

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Temperature -Relative Humidity (%RH) / Pressure Differential Record of Compression room – Every 1 hours

Temperature	Relative Humidity (%RH)	Pressure Differential
NMT 25 °C	NMT 50 % RH	NLT 0.6 mm of water

Date	27.02.24	27.02.24				
Time	2.51	3.41				
Temperature	23.4	23.2				
% RH	40.7	40.4				
Pressure Differential						
MG	1.4	1.4				
MG	2.2	2.2				
MG	1.8	1.8				
MG	2.0	2.0				
Sign	AN	AN				

MG : Magnehelic guage

Metal Detector Functioning Check (At the Start of batch):

Pass the Ferrous, Non Ferrous, Stainless steel 316 and Blank test sample disc through metal detector. Metal Detector should detect the test sample disc of Ferrous, Non Ferrous and Stainless steel 316, Blank test sample disc should not be detected.*Tick [√] whichever is applicable.

Date and Time : _____27.02.24___2.55pm___

Metal Detector Functioning Check*	Ferrous	Detected	□	Not Detected	□
	Non Ferrous	Detected	□	Not Detected	□
	Stainless steel 316	Detected	□	Not Detected	□
	Blank	Detected	□	Not Detected	□

Note : Metal detector rejects to be handled as per SOP No : SOP/PTD/025

Checked By: _____AN_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Tablet Dimension Record

Date and Time : _____

Tablet of each punch station , to be checked at the beginning of batch compression for below parameters.

Station	Length [mm]	Width [mm]	Side 1	Side 2		Station	Length [mm]	Width [mm]	Side 1	Side 2
Spec	18.5 – 18.7	8.5 – 8.7	Breakline	Plain		Spec	18.5 – 18.7	8.5 – 8.7	Breakline	Plain
1	18.61	8.57	breakline	plain		13	18.69	8.55	Breakline	Plain
2	18.61	8.57	breakline	plain		14	18.62	8.55	Breakline	Plain
3	18.61	8.57	breakline	plain		15	18.69	8.55	Breakline	Plain
4	18.61	8.57	breakline	plain		16	18.62	8.55	Breakline	Plain
5	18.61	8.57	breakline	plain		17	18.69	8.55	Breakline	Plain
6	18.61	8.57	breakline	plain		18	18.62	8.55	Breakline	Plain
7	18.61	8.57	breakline	plain		19	18.69	8.55	Breakline	Plain
8	18.61	8.57	breakline	plain		20	18.62	8.55	Breakline	Plain
9	18.61	8.57	breakline	plain		21	18.69	8.55	Breakline	Plain
10	18.61	8.57	breakline	plain		22	18.62	8.55	Breakline	Plain
11	18.61	8.57	breakline	plain		23	18.69	8.55	Breakline	Plain
12	18.61	8.57	breakline	plain						

Remark : All punches are satisfactory / not satisfactory with respect to punch dimensions and description.
In case tablet dimension of any punch station is out of limit , report to Supervisor / QA immediately.

Checked By:_____AN_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Compression Start Up Check

Date _____27.02.24_____ Time _____3.07pm_____

Group Weight of 30 Tablets (29.40 – 30.60 gm) :30.049

Machine Speed in rpm (18 – 22 rpm): 20

Friability (NMT 1 % w/w) and Disintegration Time (NMT 15 minutes) : 3.07

Friability Observations				Disintegration Time
Initial Weight in gm	Weight after Test in gm	Loss in weight in gm	% Friability	
20.029	19.983	0.046	0.23	22"

Hardness (NLT 8 Kg / cm^2) and Thickness(6.3 – 6.9 mm)

	1	2	3	4	5	Range
Hardness	19	18	19	18	19	18
Thickness	6.59	6.55	6.59	6.55	6.59	6.55

Individual weight variation (Between 950 – 1050 mg)

Min weight :_988____ Max Weight : 1016__ Done By _____Checked By _____

Aggregate weight of 30 Tablets gm :						
	1009	**989**	**1009**	**989**	**1009**	**989**
	996	**1009**	**996**	**1009**	**996**	**1009**
Average Weight per Tablet in mg :	**1009**	**989**	**1009**	**989**	**1009**	**989**
	996	**1009**	**996**	**1009**	**996**	**1009**
_____	**1009**	**989**	**1009**	**989**	**1009**	**989**

Done and Recorded By _____AN_____ Checked By : _____QAB_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

First container weight check record

Date and Time : _____27.02.24_____

Weight record for 30 tablets pooled from first container
[Limit: ±5% of standard weight i.e. from 950 mg – 1050 mg]

1000	1001	1000	1001	1000	1001
999	995	999	995	999	995
1000	1001	1000	1001	1000	1001
999	995	999	995	999	995
1004	1009	998	1001	992	1002

Minimum Tablet weight in mg :_____992_____ Maximum Tablet Weight in mg : ___1010____

Thickness record for 30 tablets pooled from first container
[Limit: 6.3 – 6.9 mm]

6.54	6.56	6.54	6.56	6.54	6.56
6.56	6.55	6.56	6.55	6.56	6.55
6.54	6.56	6.54	6.56	6.54	6.56
6.56	6.55	6.56	6.55	6.56	6.55
6.57	6.57	6.55	6.54	6.58	6.55

Minimum Tablet Thickness in mm: ___6.54_____ Maximum Tablet Thickness in mm: ____6.58_____

Done and Recorded By :AN

Checked By _____QAB_____ Date _____27.2.24_____
[Production]

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Group Weight variation record : Date :

To be checked every	15 minutes	No. of Tablets	30	Limit	29.40 – 30.60 gm

Time	Weight in gm	Done and Recorded By	Time	Weight in gm	Done and Recorded By
3.16 pm	30.053				
3.31 pm	30.074				
3.47 pm	30.081				
4.01 pm	30.051				

Group Weight Range	
Minimum (in gm)	Maximum (in gm)
30.051	30.030

Checked By:QAB

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Friability and Disintegration Time : To be checked every 1 hour

Friability limit	NMT 1 % w/w		DT Limit	NMT 15 minutes
No. of Tablets	10 Tablets		No. of Tablets	6 Tablets

Date :

Time	Friability Observations				Disintegration Time (in minutes)	Done and Recorded By
	Initial Weight in gm	Weight after Test in gm	Loss in weight in gm	% Friability		
3.16pm	20.057	20.0910	0.038	0.19	2211	

Friability Range		Disintegration Time Range	
Minimum (%)	Maximum (%)	Minimum (minutes)	Maximum (minutes)
0.19	0.19	2211	2211

Checked By :QAB

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Speed - Hardness – Thickness Record : To be checked every 1 hour

Parameter	Speed	Hardness	Thickness
Limit	18 – 22 rpm	NLT 8 Kg / cm^2	6.3 – 6.9 mm

Date :27.02.24

Time	3.16						
Thickness	6.54						
	6.52						
	6.53						
	6.54						
	6.56						
Range							
Hardness	17						
	17						
	19						
	19						
	18						
Range							
Speed	20						
Done and Recorded By	AN						

Thickness Range (in mm)		Hardness Range(in Kg/cm^2)		Speed Range (in rpm)	
Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
6.52	6.57	17	19	20	20

Checked By :QAB

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Individual Weight Variation record

No. of Tablets / Frequency	30 Tablets / At the start of the batch and to be continued every hourly
Limit	± 5 % of the standard weight (1000 mg) i.e. from 950 mg to 1050 mg

Time : __3.24pm_Min weight : __990____ Max Weight : _1015__ Done By _AN_Checked By _QAB

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg : _____						
	1015	**1008**	**1015**	**1008**	**1015**	**1008**
	1015	**1001**	**1015**	**1001**	**1015**	**1001**
	1015	**1008**	**1015**	**1008**	**1015**	**1008**
	1015	**1001**	**1015**	**1001**	**1015**	**1001**
	1013	**1001**	**1007**	**998**	**999**	**1006**

Time : _____Min weight : _____ Max Weight : _____ Done By ____AN_Checked By _QAB__

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg : _____						

Time : _____Min weight : _____ Max Weight : _____ Done By _____Checked By _____

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg : _____						

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Last container weight check record

Date and Time : __27.02.24_____

Weight record for 30 tablets pooled from last container
[Limit: ±5% of standard weight i.e. from 950 mg – 1050 mg]

1011	1013	1011	1013	1011	1013
1006	999	1006	999	1006	999
1008	1015	1008	1015	1008	1015
1011	1013	1011	1013	1011	1013
1006	999	1006	999	1006	999

Minimum Tablet weight in mg :_____997_____ Maximum Tablet Weight in mg: _____1022_____

Thickness record for 30 tablets pooled from last container
[Limit: 6.3 – 6.9 mm]

6.52	6.53	6.54	6.54	6.54	6.54
6.51	6.55	6.53	6.53	6.53	6.53
6.52	6.53	6.52	6.53	6.52	6.53
6.51	6.55	6.51	6.55	6.51	6.55
6.54	6.55	6.54	6.55	6.54	6.55

Minimum Tablet Thickness in mm : ____6.51____ Maximum Tablet Thickness in mm : _6.56_____

Done and Recorded By :AN

Checked By _____QAB_____ Date ___27.02.24_____
[Production]

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Metal Detector Functioning Check (At the End of batch):

Pass the Ferrous, Non Ferrous, Stainless steel 316 and Blank test sample disc through metal detector. Metal Detector should detect the test sample disc of Ferrous, Non Ferrous and Stainless steel 316, Blank test sample disc should not be detected.*Tick [√] whichever is applicable.

Date and Time : __27.02.24__4.13pm____

Metal Detector Functioning Check*	Ferrous	Detected	□	Not Detected	□
	Non Ferrous	Detected	□	Not Detected	□
	Stainless steel 316	Detected	□	Not Detected	□
	Blank	Detected	□	Not Detected	□

Note : Metal detector rejects to be handled as per SOP No : SOP/PTD/025

Checked By: _____AN_____

Metal Detection Record

All compressed tablets passed through Metal Detector: Yes

Tablets rejected by metal detector : Weight of tablets _____ / Number of Tablets _____

Rejected tablets destroyed by _____

Checked By : _____QAB_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

IPQC Group Weight variation record : Date : 27.02.24

To be checked every	30 minutes	No. of Tablets	30	Limit	29.40 – 30.60 gm

Time	Weight in gm	Done and Recorded By	Time	Weight in gm	Done and Recorded By
3.20pm	30.064	SKS			
3.49pm	30.064	SKS			

Group Weight Range	
Minimum (gm)	Maximum (gm)
30.06	30.097

Checked By:SD

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

IPQC - Speed - Hardness – Thickness Record : To be checked every 1 hour

Parameter	Speed	Hardness	Thickness
Limit	18 – 22 rpm	NLT 8 Kg / cm^2	6.3 – 6.9 mm

Date : 27.02.24

Time	3.20pm						
Thickness	6.54						
	6.55						
	6.53						
	6.54						
	6.55						
Range	6.53-6.59						
Hardness	18						
	17						
	13						
	18						
	17						
Range	13-18						
Speed	20						
Done and Recorded By	SKS						

Thickness Range (in mm)		Hardness Range (in Kg/cm^2)		Speed Range (in rpm)	
Minimum	Maximum	Minimum	Maximum	Minimum	Maximum

Checked By :SD

Prepared By QA	Reviewed By Production	Approved By QA	
GSK	QAB	PBK	Page **31** of **41**

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

IPQC - Friability and Disintegration Time : To be checked every hourly

Friability limit	NMT 1 % w/w		DT Limit	NMT 15 minutes
No. of Tablets	10 Tablets		No. of Tablets	6 Tablets

Date :

Time	Friability Observations				Disintegration Time (in minutes)	Done and Recorded By
	Initial Weight in gm	Weight after Test in gm	Loss in weight in gm	% Friability		
3.20pm	20.039	20.005	0.034	0.17	2411	

Friability Range		Disintegration Time Range	
Minimum (%)	Maximum (%)	Minimum (minutes)	Maximum (minutes)
0.17	0.17	2411	2411

Checked By : SD

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

IPQC - Individual Weight Variation record

No of Tablets / Frequency	30 Tablets / At the start of the batch and to be continued every hourly
Limit	± 5 % of the standard weight (1000 mg) i.e. from 950 mg to 1050 mg

Time : _____Min weight : _____ Max Weight : _____ Done By _____Checked By _____

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg :						
	1011	**1001**	**1011**	**1001**	**1011**	**1001**
	1007	**992**	**1007**	**992**	**1007**	**992**
	1009	**998**	**1009**	**998**	**1009**	**998**
	994	**1010**	**994**	**1010**	**994**	**1010**
	1012	**1013**	**1012**	**1013**	**1012**	**1013**

Time : _____Min weight : _____ Max Weight : _____ Done By _SKS____Checked By _SD___

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg :						

Time : _____Min weight : _____ Max Weight : _____ Done By _____Checked By _____

Aggregate weight of 30 Tablets gm : / Average Weight per Tablet in mg :						

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Composite Sample Analysis – Compressed Tablets

Date _____27.04.24_____ Time _____4.32pm_____

Group Weight of 30 Tablets (29.40 – 30.60 gm) :

Friability (NMT 1 % w/w) and Disintegration Time (NMT 15 minutes) :

Friability Observations				Disintegration Time
Initial Weight in gm	Weight after Test in gm	Loss in weight in gm	% Friability	
20.045	20.002	0.043	0.21	2211

Hardness (NLT 8 Kg / cm^{2}) and Thickness (6.3 – 6.9 mm)

	1	2	3	4	5	Range
Hardness	17	13	18	19	18	17-19
Thickness	6.57	6.54	6.58	6.56	6.56	

Individual weight variation (Between 950 – 1050 mg)

Min weight :_____ Max Weight : _____ Done By _SKS____Checked By __SD__

Aggregate weight of 30 Tablets gm :						
_____	**995**	**1002**	**995**	**1002**	**995**	**1002**
Average Weight per Tablet in mg :	**1008**	**995**	**1008**	**995**	**1008**	**995**
	995	**1002**	**995**	**1002**	**995**	**1002**
_____	**1008**	**995**	**1008**	**995**	**1008**	**995**
	995	**1002**	**995**	**1002**	**995**	**1002**

Done and Recorded By _____SKS_____Checked By (QC) : _____SD_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Compression Yield Data

Drum No	1	2			Total
Gross Weight [Kg]	27.34				27.34
Tare Weight [Kg]	2.71				2.71
Net Weight [Kg]	24.63				24.63

Good Yield	Theoretical	Expected	Actual
Weight [Kg]	25.00	23.75 – 25.00	24.63
Yield [%]	100 %	95 to 100 %	98.62

Compression Activity Yield Accountability	-	As a % of batch size
Blend available for compression (in Kg)	24.91	99.64
Good Yield of compressed tablets (in Kg)	24.63	98.52
Quantity of Tablets drawn during testing (in Nos)	124	0.50
Compression rejects , including machine setting and leftover blend not compressible (destroyed) (in Kg)	0.10	0.40
Unaccountable Loss in % (NMT 0.5 % w/w of batch size)	-	0.22

Date of Completion ____27.2.24_____ Assigned Hold Time [50 days] Validity ___16.4.24___

Checked By ____QAB_____
[Production]

Compressed Tablets Released / Not Released for Coating : Sign [Quality Control] ____SD_____

Next stage activity started on _____!.3.24_____ Checked By _____QAB_____[Production]

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Instructions cum Checklist for Line Clearance of Dispensing Area / Activity

Dispensing activity to be carried as per SOP No: SOP/STD/002

Sr. No	Instructions	Observation
1	All materials pertaining to previous product removed	Yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

Equipment Name	Equipment ID	Operating Range of Balance	Calibration status of Balance	Checked By	Verified By
Balance			Done	PAD	TS
Balance			Done	PAD	TS
Laminar Air Flow			Done	PAD	TS

Line Clearance record

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
M-21		Cefixime-1403	TS	YJ	1.3.24 9.53am

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Coating Material Dispensing

Date of Dispensing : _____

Item Details	AR No	Tare Weight	Net Weight	Gross Weight	Dispensed By	Checked By
Hypromellose 2910 5mPa.s BP		19.2	400	419.2	PAD DVT	TS YJ
Standard Quantity per batch: **400 gm**						
Titanium Dioxide BP		16.2	200	216	PAD DVT	TS YJ
Standard Quantity per batch: **200 gm**						
Lake of Sunset yellow IH		16.1	50	66.1	PAD DVT	TS YJ
Standard Quantity per batch: **50 gm**						
Talc BP		16.3	100	116.3	PAD DVT	TS YJ
Standard Quantity per batch: **100 gm**						
Purified Water BP	01032024		6		SBL	
Standard Quantity per batch: **6.0 Kg**						

Above Material Received By (Production)____QAB_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Instructions cum Checklist for Line Clearance of Coating Area / Activity

Sr. No	Instructions	Observation
1	All materials pertaining to previous product removed	Yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

Name of machineries required			
Equipment Name	Equipment ID	Checked By	Verified By
SS container			
Auto-coater	MX064		
Stirrer	MX109		
Colloid mill	MX148		
Balance	MX302, MX306,MX050		

Line Clearance record

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
	Cefixime Tablets USP 400 mg	ELEAF24002			

Coating solution preparation and coating activity done / performed by:SBL

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Coating Solution Preparation and Coating activity

Temperature – Relative Humidity (%RH) / Pressure Differential Record of Coating room – Every 1 hours

Temperature	Relative Humidity (%RH)	Pressure Differential
NMT 25 °C	NMT 50 % RH	NLT 0.6 mm of water

Date	1.3.24	1.3.24	1.3.24			
Time	10.31am	11.34am	12.37pm			
Temperature	21.5	22.2	21.1			
% RH	42.8	43	41.9			
Pressure Differential						
MG	1.4	1.4	1.4			
MG	1	1	1			
Sign	QAB	QAB	QAB			

MG : Magnehelic guage

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Coating Solution Preparation

Date of Coating Solution Preparation __1.3.24_____

Note : The coating solution should be freshly prepared and consumed immediately. The coating solution shall not be held after preparation.
The entire quantity of coating solution prepared is to be sprayed.

I	Activity	Standard / Recommended	Observation / Actual	Time From - To	Done by	Checked By
1	Weight Checking of Dispensed Material	-	done	10.35-10.40am	SBL	QAB
2	Take 5 Kgs of Purified water in SS vessel	-	done	10.45-10.50am	SBL	QAB
3	Dissolve in it under stirring 400 gm HPMC 5 cps 200 gm of Titanium Dioxide 50 gm of Lake of Sunset yellow and 100 gm of Talc	-	done	10.55-11.00am	SBL	QAB
4	Mix to form uniform dispersion	15 min	done	10.35-10.40am	SBL	QAB
5	Stir and homogenize the solution through Colloidal Mill and Rinse the colloid mill with 1 Kg of Purified water	5 minutes	done	10.35-10.40am	SBL	QAB

Note : Maintain stirring of the coating solution all throughout the coating process.

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Coating Process Parameters

Date : ___1.03.24_____ Time Started __11.32am___ Time Completed ___12.46 am_____

Tablet Load to be between 23.75 – 25.00 Kg.

Actual Tablet Load : _____24.63 kg_____ Checked By ____QAB_____

Distance between Spray Gun Nozzle and Tablet Bed to be between 16 – 22 cm .

Actual Distance between Spray Gun Nozzle and Tablet Bed : __20cm_____ Checked By ___QAB_____

Note : Coating In Process Parameters to be recorded every hourly

No	Parameter	Range / Limit	Observation	Observation	Observation	Observation	Observation
	Time	-					
1	Pan rpm	2 - 7	5-8	5-8	5-8		
2	Inlet blower rpm	800 – 3000	2600	2600	2600		
3	Exhaust blower rpm	700 – 2400	1500	1500	1500		
4	Pressure [as mm of water]	3 – 15 mm	3-5	3-5	3-5		
5	Bed Temperature	45 – 60 °C	45	45	45		
6	Inlet Air Temperature	50 - 60 °C	54	54	54		
7	Exhaust Air Temperature	40 - 50 °C	42	42	42		
8	RPM of peristaltic pump [Dosing]	40 – 65	42	42	42		
9	Spraying pressure [Atomization]	1.5–6 Kg/cm^2	2	2	2		
10	Fan air	1 – 2 Kg/ cm^2	1	1	1		
11	Nozzle Blocked / Clear	To be clear	clear	clear	clear		
	Checked By	-	QAB	QAB	QAB		

Drying Record

Standard	Drying Time [1/2 hour to 1 hour]	Drying RPM [1 – 2]	Checked By
Actual	**12.46pm-1.20pm**	**1.5**	**QAB**

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Composite Sample Analysis – Coated Tablets

Description of Coated Tablets : Complies / Not complies
Orange colored ,film coated, capsule shaped tablet with breakline on one side and plain on other side.

Determination of weight gain per tablet :

	I	II	III	IV	V	Average	Done and recorded by
Weight of 20 Tablets before coating (A)	20.019	20.042	20.054	20.014	20.041	1001.52	AN
Weight of 20 Tablets after coating (B)	20.019	20.045	20.054	20.014	20.041	1001.52	AN
Weight Gain in mg (Between 20 to 30 mg per tablet)			Average (B) – Average (A): 21.34				AN
Weight Gain in % (Between 2.0 to 3.0 % w/w)			2.1				AN

Disintegration Time : [NMT 30 minutes]

Length of Tablet (18.55 – 18.75 mm) / Width of Tablet (8.55 – 8.75 mm) /Thickness (6.3 – 6.9 mm)

	1	2	3	4	5	Range
Length	18.69	18.70	18.69	18.70	18.69	18.70
Width	8.68	8.60	8.68	8.60	8.68	8.60
Thickness	6.65	6.59	6.65	6.59	6.65	6.59

Coated Tablet : Individual weight variation record : Within 978.5 mg to 1081.5 mg

Min weight :_1009____ Max Weight : _1045__ Done By __SKS____Checked By _SD____

Aggregate weight of 30 Tablets gm :						
	1025	**1042**	**1021**	**1024**	**1028**	**1012**
	1012	**1023**	**1025**	**1042**	**1025**	**1042**
Average Weight per Tablet in mg :	**1013**	**1020**	**1012**	**1023**	**1013**	**1020**
	1014	**1013**	**1025**	**1042**	**1014**	**1013**
_____	**1024**	**1028**	**1012**	**1023**	**1013**	**1020**

Done and Recorded By _____SKS_____Checked By (QC) : _____SD_____

Batch Record (Manufacturing)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Coating Yield Data

Drum No	1	2			Total
Gross Weight [Kg]	27.74				27.74
Tare Weight [Kg]	2.62				2.62
Net Weight [Kg]	25.12				25.12

Good Yield	Theoretical	Expected	Actual
Weight [Kg]	25.75	24.46 – 25.75	25.12
Yield [%]	100 %	95 to 100 %	97.55

Coating Activity Yield Accountability	-	As a % of batch size
Tablets available for Coating (in Kg)	24.63	98.52
Yield of Coated tablets (in Kg)	25.12	97.55
Quantity of Tablets drawn during testing (in Nos)	200	0.80
Coating Rejects (destroyed) (in Kg)		
Unaccountable Loss in % (NMT 0.5 % w/w of batch size)	-	0.17

Date of Completion ___1.03.24_____ Assigned Hold Time [50 days] Validity ____19.04.24_____

Checked By _____QAB_____
[Production]

Coated Tablets Released / Not Released for Packing : Sign [Quality Control] ____SD_____

Next stage activity started on ____5.3.24_____ Checked By ____VS_____[Production]

Batch Manufacturing completed Sign: _____QAB_____ Date:____1.3.24_____

Maxim Pharmaceuticals Pvt. Ltd.

Batch Record (Packaging Plan)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Batch Packing Plan

Summary of packaging

Brand Name	Country	Quantity of tablets planned to be packed	Country Specific Shelf Life	Expiry Date as per Shelf Life
Cefrown 400	Peru	2500 Tablets	36 months	ENE2024

Sign (Packaging) _____VS_____ Checked By (Quality Assurance) _____GSK_____

Brand Name	Country	Quantity of tablets planned to be packed	Country Specific Shelf Life	Expiry Date as per Shelf Life

Sign (Packaging) _____ Checked By (Quality Assurance) _____

Brand Name	Country	Quantity of tablets planned to be packed	Country Specific Shelf Life	Expiry Date as per Shelf Life

Sign (Packaging) _____ Checked By (Quality Assurance) _____

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Packing Details

Brand Name	Cefrom 400
Country	Peru
Quantity planned to be packed	25000 tablets1
No. of Tablets per blister	10 tablets
No. of blisters per monocarton	1 blisters
No. of monocartons per shrink	5 monocartons
No. of shrink per shipper	27
Product Storage Condition	Less than 30 c

Recorded By : _____AN_____ Checked By (Packaging) _____VS_____

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Primary Packing Material Dispensing Sheet

Date of Issue_____5.3.24_____

Quantity Planned to be packed _____25000 tablets_____

-	Printed Blister Foil	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Brand Name	Cefrom 200	99A3165	4.1		1.2	2,9
Quantity required for plan in Kg	3					
-	Total	-	4.1		1.2	2.9

-	Base Foil	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Base Foil Width in mm	292mm	MP32913	27.1		18	9
Quantity required for plan in Kg	9					
-	Total	-	27.1		18	9

Above Material Dispensed By (Stores) ___RB_____ Above Material Received By (Packaging)__VS ___

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Secondary and Tertiary Packing Material Dispensing Sheet

Date of Issue____5.3.24_____

-	Carton	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Brand Name	Cefrom 400	99A3316	2500			2500
Quantity required for plan in Nos.	2500					
-	Total	-	2500			2500

Date of Issue__5.3.24_____

-	Leaflet	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Brand Name	Cefrom 400	99A3316	2500			2500
Quantity required for plan in Nos.	2500					
-	Total	-	2500			2500

Above Material Dispensed By (Stores) ___RB_____ Above Material Received By (Packaging)____VS__

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Secondary and Tertiary Packing Material Dispensing Sheet

Date of Issue_____5.3.24_____

-	Outer Carton / Shrink	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Brand Name	280mm	MP32987A	1			1
Quantity required for plan in Nos. / Kg	1					
-	Total	-	1			1

Date of Issue_____5.3.24 _____

-	Shipper	AR No	Issued Quantity	Excess Issued	Excess Returned	Net Consumed
Shipper Code	M92	99A3156	19		1	18
Quantity required for plan in Nos.	19					
-	Total	-	19		1	18

Above Material Dispensed By (Stores) __RB___ Above Material Received By (Packaging)___vs___

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Instructions cum Checklist for Line Clearance of Tablet Inspection and Blister Packing Area / Activity

Sr. No	Instructions	Observation
1	All materials pertaining to previous product , including stereos removed	yes
2	All documents pertaining to previous product removed	yes
3	Any other material / document not relevant for the batch to be removed	yes
4	Environmental requirements are within limits before beginning operations	yes
5	Working area is cleaned.	yes
6	All required equipment are clean and suitable for use	yes
7	Balances to be used are calibrated	yes

Name of machineries required			
Equipment Name	Equipment ID	Checked By	Verified By
Tablet / Capsule Inspection Machine	MX288	AN	VS
Blister Packing Machine	MX233	AN	VS
Balance(s)	MX097,MX209	AN	VS
Line No.	04	AN	VS
Cartonator	MX258	AN	VS
Checkweigher	MX197	AN	VS
Shrink wrapping Machine	MX088	AN	VS

Line Clearance record for Primary Packaging Area and its line

Room No	Previous product	Previous product batch No	Above observation Checked and Recorded By & Date	Above observation Verified by (IPQC)	Date and Time of Verification
M17	Cefrom 400	ElEAF24002	AN	PB	5.3.24 10 am

Blister Packing done by : ARD

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Temperature -Humidity / Pressure Differential Record of Blister Packing room – Every 1 hours

Temperature	Humidity	Pressure Differential
NMT 25 °C	NMT 50 % RH	NLT 0.6 mm

Date	5.03.24	5.03.24				
Time	10.09 am	11.06 am				
Temperature	22.7	23				
Humidity	42.8	43.1				
Pressure Differential						
MG	1.6	1.6				
MG	1.8	1.6				
MG	1.6	1.4				
MG	1.6	1.4				
MG	1.6	2				AN
Sign	AN	AN				5.3.24

MG : Magnehelic guage

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Tablet Inspection Record

Inspection done by :

Date	Time of inspection From - to	Name of the person who carried out Inspection activity	Drum Numbers Inspected
5.3.24	10.12 am – 10.40 am	Gayatri Gadhave	1/9

Inspect all tablets for possible defects such as capping, sticking, mottling, broken tablets ,mix up tablets , black spot , joint tablets. After inspection record the weights of good and rejection tablets.

	Weight of Tablets in Kg
Total Coated Tablets taken for inspection	25.12
Good Tablets obtained after inspection	24.83
Total Rejection Tablets after Inspection	0.29
Given below details of rejection	
Joint Tablets	0.13
Broken Tablets	0.12
Tablets with black spots	
Tablets with capping	
Mix up Tablets	
Any other defect left over tablets	0.04

Rejected Tablets destroyed by _____ABD_____ Date ____5.3.24_____ Time ___11.45 am___

Destruction of rejected tablets checked By:_____VS_____

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Blister Packing

Date :

Approval of Overprinting Matter on Foil

Matter	Foil		Specimen checked By
	Preprinted	To be printed	
Batch No		ELEAF20024	
Mfg Date		FEB 2024	Packaging
Expiry Date		ENE 2027	Specimen Verified By
Mfg Lic. No	PD/72		
Reg. No	EE - 10998		
Any other Matter			QA

Blister Packing Process Parameters and Observation

Frequency – At the beginning of blister packing and every roll change and every 1 hours

		Date	5.3.24	5.3.24		
		Time	10.35 am	11.17 am		
Parameter		Standard/ Limit				
1	Machine Speed	18 - 34 punches per minute	20	20		
2	Temp. of sealing roller	Between 180 – 220 °C	204 c	204 c		
3	Depth of forming punch	Between 11 - 13	12.60	12.60		
4	Leak test	No pocket should leak in 4* 10 T	Nil	Nil		
5	Perforation suitability	Adequate	Yes	Yes		
6	Overprinting Matter	To be correct and legible	Yes	Yes		
	Checked By	-	AN	AN		

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Carton Packing

Date :

Approval of Overprinting Matter on Carton

Matter	Carton		Specimen checked By
	Preprinted	To be printed	VS
Batch No		ELEAF24002	
Mfg Date		FEB 2024	Packaging
Expiry Date		ENE 2027	Specimen Verified By
Mfg. Lic. No	PD/72		
Reg. No	EE-10998		AN
Any other Matter			QA

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Acceptable weight range determination for Carton weight check

Sr. No.	Parameter	Observation	
1	Total weight of 10 blisters in gm	140	-
2	Average weight per blister in gm	14	-
3	No of blisters per carton	1 blister	-
4	Total weight of blister per carton in gm		14
5	Total weight of 10 cartons in gm	108	-
6	Average weight per carton in gm	-	10.8
7	Total weight of 10 leaflets in gm	22	-
8	Average weight per leaflet in gm	-	2.2
9	Weight of Filled Carton in gm	-	27
10	Acceptable lower weight = Weight of Filled Carton Less weight of leaflet		**24.8**
	Acceptable upper weight = Weight of Filled Carton plus weight of leaflet		**29.2**

Check-weigher working is confirmed as follows

Carton with blister but no leaflet passed Accepted / Rejected by check-weigher

Carton with no blister passed Accepted / Rejected by check-weigher

Done By _____AN_____ Checked By____VS____

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Mono-carton Carton Packing Parameters and Observation

Frequency – At the beginning of packing and every 1 hours

		Date	5.3.24	5.3.24		
		Time	10.43am	11.34am		
Parameter		Standard/ Limit				
1	No. of Blisters per carton	1	1	1		
2	Overprinting Matter	To be correct and legible	Yes	yes		
3	Weight check of filled carton		27	27.2		
4	Checked By	-	VS	VS		

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Acceptable weight determination for Outer Carton / Shrink weight check

Sr. No.	Parameter	Observation	
1	Total weight of 10 Outer cartons in gm	na	-
2	Average weight per Outer carton in gm	-	na
3	Average weight of one monocarton in gm	27	-
4	No. of monocartons per Outer Carton /Shrink	5	-
5	Total weight of monocartons in gm	-	135
6	Weight of Filled Outer Carton / Shrink in gm	-	136
Acceptable weight = Weight of outer Carton / Shrink ± weight of one monocarton , in gm			109-163

Done By _____AN_____ Checked By_____VS_____

Outer Carton / Shrink Packing Parameters and Observation :

Frequency – At the beginning of packing and every 1 hours

		Date	5.3.24	5.3.24		
		Time	10.15am	11.42am		
Parameter		Standard/ Limit				
1	No. of Monocarton per Shrink	5	5	5		
2	Overprinting Matter	To be correct and legible				
3	Weight check of filled Outer carton / Shrink	136	13.62	13.62		
4	Checked By	-	VS	VS		

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Acceptable weight range determination [Shipper]

Sr. No.	Parameter	Standard / Limit
1	Weight of empty shipper (Kg)	**1.300**
2	Weight of Outer Carton / Shrink in gm	**136.0**
3	No. of Outer cartons / Shrinks per shipper	**27**
4	Weight of full shipper (Kg)	**4.37**
5	Acceptable weight per shipper (Kg) is Weight of full shipper less weight of one outer carton / Shrink	NLT 4.835

Done By _____AN_____ Checked By_____VS_____

Shipper Weighing Record

Shipper No.	Gross weight (Kg)	Shipper No.	Gross weight (Kg)	Shipper No.	Gross weight (Kg)	Shipper No.	Gross weight (Kg)	Shipper No.	Gross weight (Kg)
36	**4,970**	**46**	**4.970**						
37	**4.970**	**47**	**4.975**						
38	**4.975**	**48**	**4,970**						
39	**4,970**	**49**	**4.970**						
40	**4.970**	**50**	**4.975**						
41	**4.975**	**51**	**4.970**						
42	**4,970**	**52**	**4.975**						
43	**4.970**								
44	**4.975**								
45	**4,970**								

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Shipper Weighing Record

Minimum weight of Full Shipper in Kg : 4.960

Maximum Weight of Full Shipper in Kg : 4.985

Loose Shipper Number : 53

Loose shipper quantity:_____12x5x1xIoT_____ Loose shipper weight in Kg :___3.490____

Total Quantity Packed :

Done and Recorded By _____MS_____ Checked By_____VS_____

Batch Record (Packaging)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	
	Brand Name	
	Country	

Primary Packing Material Reconciliation

Item	Quantity in Kg
Quantity of Blister Foil Consumed	2.9000
Quantity of Base Foil Consumed	9
Total Quantity of Foil Consumed [Blister + Base]	11.9
Theoretical quantity of foil required = Weight of foil per blister * Number of Blisters	9.2
Total quantity of foil used in machine setting / roll changeover / printing setting	2.72

Rejected Quantity Destroyed By _____ABD_____ Checked By _____VS_____

Secondary and Tertiary Packing Material Reconciliation

Item	Total quantity Consumed	Quantity used for Packing	Quantity Rejected	Rejected quantity destroyed by	Checked By
Carton in Nos.	2500	2384	116	Moni sahani	
Leaflet in Nos.	2500	2384	116	Moni sahani	
Outer Carton in Nos.					
Shipper in Nos.	18	18			

Batch Packaging Completed Sign:_____VS_____ Date:_____5.3.24_____

Batch Record (Release)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Batch Release Record

Review the following documents:

- Dispensing Record yes
- Manufacturing Record yes
- Inspection Record yes
- Packing Record yes
- Packing Material Reconciliation yes
- Yield data yes
- Analytical data yes
- Certificate of Analysis yes
- Deviations , if any done in the batch yes

As the reviewed documents are satisfactory / not satisfactory , the batch is allowed / not allowed to be dispatched.

Quantity released / not released for dispatch 2355xIOT

Management Executive – Quality Assurance Date: -------13.03.24----------

Batch Record (Blend In process Analysis Record)

Product Name	BMR Ref No.	BMR 421 0823 V01
Cefixime Tablets USP 400 mg	Batch No.	

Annexure 1

Blend - In-Process Analysis Record

Parameter	Observation	Standard / Limit
Description	complies	White to off white colored free flowing blend
Water Content	6.75%	NMT 10 % w/w
Particle Size	100% pass	100 % should pass through 20 #

Water Content – Data

	Na Tartrate # 1	Na Tartrate # 2	Sample
Wt in mg	163.2	163.5	503.9
Titration reading [TR] in ml	4.29	4,34	5.74
Factor	5.973	5.8995	
Average Factor :		Water Content	

Blend released for Compression on _____PBK_____

[Quality Control]