Master Formula Record

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.
MFR No.	MFR 421 0823 V01
Batch Size	25000 Tablets

Master Formula Record

Product Name	**MFR No.**
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

APPROVAL PAGE

Plant Location:

Maxim Pharmaceuticals Pvt. Ltd.

Gat No 1251-1261, Alandi Markal Road, Markal – Khed – Pune 412105

RESPONSIBILITIES	**SIGNATURE**	**DATE**
Prepared by: (ME Quality Assurance)		
Reviewed by: (Head Production)		
Reviewed by: (Head Quality Control)		
Approved by: (Head Quality Assurance)		

Effective Date	**:**	

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

TABLE OF CONTENTS

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

GENERAL INFORMATION

Name of the Product	Cefixime Tablets USP 400 mg
Dosage Form	Tablets
Label claim	Each film coated tablet contains Cefixime USP (as trihydrate) equivalent to Anhydrous Cefixime 400 mg
Shelf Life	36 Months
B. size	0.25 Lac Tablets
Therapeutic category	Cephalosporin antibiotic
Product pack	A blister of 10 Tablets
License No.	PD / 72
Storage Condition	Store in well closed container, protected from light, at temperature not exceeding 30°C.

Applicable to Brand Name	Finished product specification Reference
CEFROM 400	FPS504

Batch Numbering System :
B. No. ELEAF23001

Where,
First digit that is E , represents for Export
Second digit that is L, represents for Latin American
Third digit that is E, represents for molecule Cefixime
Fourth digit that is A, represents for strength 400 mg
Fifth digit that is F, represents for dosage form – Film coated tablets
Next two digits that is 23 , represents calendar year (eg. For 2023 it is 23)
Next three digits that is 001, represents serial number of the batch in a given calendar year

Accordingly for the first batch of the year 2023 , batch number shall be ELEAF23001

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

STAGES OF MANUFACTURING PROCESS WITH YIELDS

No.	STAGE
1	DISPENSED MATERIAL

Requirements for storage :

- Dispensed material is to be stored in day store at a temperature not exceeding 25°C and relative humidity NMT 65 %.
- Dispensed material is packed in double polybag with issue label & placed in HDPE drum.

No.	STAGE	THEORITICAL YIELD % OF BATCH SIZE	EXPECTED YIELD % OF BATCH SIZE
1	BLEND	100 %	96 – 100 %
2	COMPRESSED TABLETS	100 %	95 – 100 %
3	COATED TABLETS	100 %	95 – 100 %

Requirements for storage :

- Intermediate stages namely blend, compressed tablets and coated tablets is to be stored in intermediate store at a temperature not exceeding 25°C and relative humidity NMT 65 %.
- Intermediate stage material is placed in double polybag & placed in HDPE drum.
- Each drum is labelled with product name, batch number, stage, Mfg. date, weight in Kg.
- All the drums of one batch are linked with chain.

No.	STAGE	THEORITICAL YIELD % OF BATCH SIZE	EXPECTED YIELD % OF BATCH SIZE
1	FINISHED PACK	100 %	95 – 100 %

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

GENERAL INSTRUCTIONS FOR MANUFACTURING

Sr. No.	Instructions
1	Go through the entire document before commencement of manufacturing activities
2	Nose mask and gloves to be worn / used appropriately during operation involving material handling.
3	All machinery should be cleaned and dried before use. It should be checked by responsible Management Executive.
4	Working area should be cleaned before use
5	Proper line clearance must be obtained before commencing any operation wherein it is checked that
	All materials pertaining to previous product removed
	All documents pertaining to previous product removed
	Any other material / document not relevant for the batch to be removed
6	Equipment and Instrument requiring calibration should bear valid calibration status.
7	Ensure that temperature NMT 25°C and relative humidity NMT 50 % in areas where material is exposed to environment, unless otherwise specified
8	Whenever the actual weight is not within limits of expected weight , please review before further processing
9	Report any deviation from the procedure to Head of the Department / QA Department

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

AREAS REQUIRED

Dispensing
Granulation / Blending
Compression
Coating
Tablets Inspection
Alu Alu Blister Packing

MAJOR EQUIPMENT REQUIRED

Equipment	Ref. SOP No. for Operation	Ref. SOP No. for Assembling and Cleaning
Balance	SOP/PRD/006 & SOP/PRD/004	-
Reverse Laminar air flow	SOP/STD/008	SOP/STD/014
Sieves 20 #, 80 #	SOP/PTD/002	SOP/PRD/015
Sifter 20"	SOP/PTD/001	SOP/PTD/002
Planetary Mixer (200 L)	SOP/PTD/003	SOP/PTD/004
23 Station single rotary compression machine	SOP/PTD/011	SOP/PTD/011
Metal Detector cum Dedustor	SOP/PTD/025	-
Punch set (18.5 X 8.5 , Capsule shape, Upper punch with Breakline, Lower punch -plain)	SOP/PRD/013	SOP/PRD/013
Autocoater	SOP/PTD/019	SOP/PTD/020
Colloid mill	SOP/PTD/015	SOP/PTD/015
Tablets Inspection Machine	SOP/PKG/014	SOP/PKG/014
Alu Alu Blister packing Machine	SOP/PKG/008	SOP/PKG/009

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

MANUFACTURING FORMULA

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

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

$ Does not appear in final product

Note: Sources of all materials used should be as per approved vendor list

EXPIRY DATE ASSIGNMENT

The shelf life of the product is 36 months

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

GRANULATION /BLENDING:

I	EQUIPMENT CLEANING Refer Line Clearance sheet

I	Activity	Standard / Recommended
1	Weight Checking of Dispensed Material	Weight Checking
2	Sifting : Cefixime Trihydrate 11.19 Kg	20 #
3	Simultaneous Sifting: Microcrystalline Cellulose 10.41 Kg Anhydrous Lactose 2.5 Kg Croscarmellose Sodium 0.6 Kg	20 #
4	Simultaneous Sifting : Material sifted at step 2 and 3 and load in PLM bowl	20 #
5	Blending : Material in PLM bowl at step 4	Slow speed 25 minutes
6	Sifting Magnesium Stearate 300 gm	80 #
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	
8	Lubrication : Material in PLM bowl after step 7	Slow Speed 3 minutes
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.	

Master Formula Record

Product Name	MFR No.
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YIELD AND INPROCESS CHECKS AT BLEND STAGE

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

In Process Checks:

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

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

COMPRESSION

Area and Equipment Clearance

Proceed after obtaining line clearance. Compress Lubricated granules using the Machine / Punch set detailed below

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	NMT 50 % RH

Parameters	Specification
Intended Wt 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

Temperature, Humidity and Pressure Differential to be monitored every 1 hour and its record maintained

Master Formula Record

Product Name	MFR No.
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Metal Detector Functioning Check:

Functioning of the metal detector to be checked at the start up , first and last container of the batch as follows

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.

Record the weight of the tablet rejected by metal detector.

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

YIELD AFTER COMPRESSION

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

In Process Checks :

Parameter	**Standard / Limit**
Description of compressed tablets	White to off white colored capsule shaped, uncoated tablet with breakline on one side and plain on other side
Average Weight per tablet	1000 mg $\pm$ 2 % [980 – 1020 mg]
Individual weight variation	950 – 1050 mg
Length	18.5 – 18.7 mm
Width	8.5 – 8.7 mm
Thickness	6.3 – 6.9 mm
Hardness	Between 10 - 20 Kg / cm^2
Friability	NMT 1 % w/w
Disintegration Time	NMT 15 minutes

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

COATING

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	AREA & EQUIPMENT CLEANING
	After getting line clearance proceed further

I	Preparation of coating solution	Standard / Recommended
1	Weight Checking of Dispensed Material	-
2	Take 5 Kgs of Purified water in SS vessel	-
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	-
4	Mix to form uniform dispersion	15 min
5	Stir and homogenize the solution through Colloidal Mill and Rinse the colloid mill with 1 Kg of Purified water	5 minutes

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

Master Formula Record

Product Name	MFR No.
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Coating Process Parameter

For each lot - Tablet Load to be between 23.75 – 25.00 Kg
Distance between Spray Gun Nozzle and Tablet Bed to be between 16 – 22 cm .

Note : Coating Process Parameters to be recorded every hourly

1. Switch on the hot air system, and set the inlet temperature to about 45 to 60° C
2. Start the pan and allow the tablet bed to warm for about 15 minutes by putting the inlet blower
3. Spray the film coating solution on the tablet cores maintaining the below listed process parameters

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

Master Formula Record

Product Name	MFR No.
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YIELD AND INPROCESS CHECKS AFTER COATING

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

In Process Checks :

Parameter	**Standard / Limit**
Description of coated tablets	Orange colored, film coated, capsule shaped tablet with breakline on one side and plain on other side.
Average Weight per tablet	1030 mg $\pm$ 3 % [999.1 – 1060.9 mg]
Individual weight variation	978.5 – 1081.5 mg
Disintegration Time	NMT 30 min
Weight gain	20 - 30 mg

Master Formula Record

Product Name	MFR No.
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PACKING

Standard quantity of primary packing material for full batch size

Sr. No	Item	Unit	Std Qty / batch
1	Printed Blister foil	Kg	3.0
2	Base foil	Kg	9.0

Standard quantity of secondary and tertiary packing material for full batch size

3	Carton	Nos.	Will depend on packing configuration
4	Leaflet	Nos.	
5	Outer Carton / Shrink	Nos.	
6	Shipper	Nos.	

Master Formula Record

Product Name	MFR No.
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GENERAL INSTRUCTIONS FOR TABLET INSPECTION AND BLISTER PACKING ACTIVITY

Sr. No.	Instructions
1	Go through the entire document before commencement of manufacturing activities
2	Nose mask and gloves to be worn / used appropriately during operation involving material handling.
3	All machinery should be cleaned and dried before use. It should be checked by responsible Management Executive.
4	Working area should be cleaned before use
5	Proper line clearance must be obtained before commencing any operation wherein it is checked that
	All materials pertaining to previous product removed
	All documents pertaining to previous product removed
	Any other material / document not relevant for the batch to be removed
	In case of packaging activity, stereos of previous product are removed
6	Equipment and Instrument requiring calibration should bear valid calibration status.
7	Ensure that temperature NMT 25°C and relative humidity NMT 50 % in areas where material is exposed to environment, unless otherwise specified

Master Formula Record

Product Name	MFR No.
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TABLET INSPECTION

Inspection :

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 tablets and rejection tablets.

Sorting

During inspection the coated tablets are to be bifurcated into the following

Good Tablets - The tablets which are satisfactory and to be used for packing

Rejection Tablets – The tablets that are not suitable for use and are to be destroyed , eg having black spots / foreign matter, joint tablets, broken tablets, tablets with capping.

Tablet inspection activity to be done by qualified inspector.
After Inspection and sorting record the weight of good tablets and rejected tablets. Record the details of rejected tablets based on its nature.
Record destruction of rejected tablets.

Master Formula Record

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Overprinting of Foil, Carton and Shipper label

Before proceeding with the batch overprinting,

1. Environmental conditions to be maintained.
2. Overprinted specimen is to be duly signed by Management Executive Packaging for correctness and confirmed by Management Executive Quality Assurance. The same is to be retained with the batch document

For Sale Pack overprinting has to be done on the following

Overprinting to be done on	Matter to be overprinted if not preprinted
Aluminum Foil / Carton	Batch No Mfg Date Exp Date Mfg. Lic. No. Reg. No. Any other matter

Master Formula Record

Product Name	MFR No.
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Alu Alu Blister Packing

I Area and Equipment Clearance
After getting line clearance proceed further

1. Transfer the required aluminum foil and stereos to the blister packing area
2. As mentioned above, specimen of the overprinted foil is to be duly signed by Production and Quality Control / Assurance
3. On approval of the overprinted matter, proceed with batch blister packing maintaining the following

Parameter		Standard/ Limit	Frequency
1	Machine Speed	18 – 34 punches per minute	At the beginning of blister packing and every roll change and every 1 hours
2	Depth of Forming Punch	11 - 13	
3	Temp. of sealing roller	Between 180 – 220 °C	
4	Leak test	No pocket should leak in 4* 10 T	
5	Perforation Suitability	Adequate	
6	Overprinting Matter	To be correct and legible	

Before packing the blisters into the carton, on line checking is to be done and if any defective blisters obtained , the same are to be removed and feedback to be given for doing the needful in machine setting / operation.
The defective blisters are to be cut open and tablets checked and if satisfactory may be packed. Care is to be taken for absence of foil pieces, broken tablets and other foreign matter, before packing.
Further packing of the blisters to be done in cartons and cartons to be packed in Shippers as per packing description. Check and record packing suitability every 1 hours

Excess packaging material

After batch packing is completed , Management Executive has to determine accountability of use of the packaging material. The excess overprinted packaging material is to be destroyed / quarantined for destructions as per SOP No. SOP/PKG/004
The excess packaging material [without overprinting] is to be returned to stores with label of Return from Production.

Master Formula Record

Product Name	MFR No.
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ACCOUNTABILITY / RECONCILIATION OF BATCH

After completion of packaging activity ascertain the number of tablets packed and determine the yield obtained

Accountability is calculated as follows

[Qty transferred to BSR + Samples [Control , Analytical ,Observation , Stability and Party]] * 100 divided by Batch size

Master Formula Record

Product Name	MFR No.
Cefixime Tablets USP 400 mg	MFR 421 0823 V01

BATCH RELEASE

Before release of batch for dispatch,

1. The BMR shall be reviewed by management executive QA and checked for the following
   - Dispensing Record
   - Manufacturing Record
   - Inspection Record
   - Packing Record
   - Packing Material Reconciliation
   - Yield data
   - Analytical data
   - Certificate of Analysis
   - Deviations , if any done in the batch

2. After dispatch record details of Invoice No. , Dispatch date, Quantity dispatched on batch summary sheet.