

East African India Overseas

On behalf of M/s Precise Bio Pharma Private Limited
8, Pharma City, Selaqui, Dehradun - 248011

Finished Goods				
Name of Product	POLAZI		Report No	PRE-09240296/F
Generic Name	Polmacoxib Capsule 2 mg		Reference No.	CF-0004/24-25
Specification No.	PADL/FP/SPC/013-02		Date of Receipt	06/09/2024
Manufactured By	East African (I) Overseas		Date of Analysis	06/09/2024
Page No.	1/2		Date of Release	14/09/2024
Batch No.	Batch Size	Date of Mfg.	Date of Exp.	Sample Qty
ECPC2410A	10,00,000 Capsules	08/2024	07/2026	300 Capsules

Sr. No	PARAMETERS	SPECIFICATIONS	RESULTS
01	Description	Size 4 Hard gelatin capsule with pink cap and transparent body filled with off white to creamish granular powder.	Size 4 Hard gelatin capsule with pink cap and transparent body filled with off white granular powder.
02	Identification: By HPLC	The retention time of major peak in the chromatogram of the test solution corresponds to that in chromatogram of the standard preparation as obtained in the assay.	The retention time of major peak in the chromatogram of the test solution corresponds to that in chromatogram of the standard preparation as obtained in the assay.
03	Average weight of filled capsules	135.0 mg $\pm$ 10 % (121.5 mg to 148.5 mg)	134.92 mg
04	Average Net fill weight	95.0 mg $\pm$ 10 % (85.5 mg to 104.5 mg)	95.31 mg
05	Uniformity of fill weight	Not more than two of the individual mass contents deviate from the average net mass by more than $\pm$ 10 % and none deviates by more $\pm$ 20 %	- 3.30 % to + 2.06 %
06	Disintegration time	Not more than 30 minutes	02 minutes 35 seconds
07	Dissolution Test	Not less than 75 % (Q) in 45 minutes	95.45 % to 99.97 %
08	Related Substances Any Individual Unknown Impurity Total impurities	Not more than 0.5 % Not more than 1.5 %	0.1172 % 0.4003 %

Remarks : In the Opinion of the under signed, the sample referred to above is of /is not of standard quality as per IP, USP, BP, BIS, IHS, as defined in the act and the rules made there under.

	Analyzed By	Checked by	Approved by
Designation	Under officer	Manager QC	Manager QA
Sign	Chalini		
Date	14/09/2024	14/09/2024	14/09/2024

Format No. QC02-F08-01

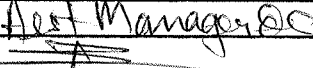
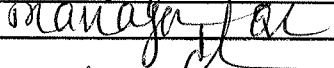
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Sr. No	PARAMETERS	SPECIFICATIONS	RESULTS
09	Residual Solvents Acetone	Not more than 5000 ppm	573.17 ppm
10	Content Uniformity	Limit (L1): Should be less than or equal to 15.0] [Limit (L2): Should be less than or equal to 25.0]	3.96
11	Assay (By HPLC)	Between 90.0 % to 110.0 %	101.15 %
12	Microbial Limit Test A) Total Aerobic Microbial Count B) Total yeast & mold count C) E. coli	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent in 1 g	25 cfu/g Less than 10 cfu/g Absent in 1 g

Remarks : In the Opinion of the under signed, the sample referred to above is of /is not of standard quality as per IP, USP, BP, BIS, IHS, as defined in the act and the rules made there under.

	Analyzed By	Checked by	Approved by
Designation	Junior officer	Asst Manager QC	Manager QA
Sign	Oralini		
Date	14/09/2024	14/09/2024	14/09/2024

Format No. QC02-F08-01