



BANGALORE | HONG KONG | JOHANNESBURG | LONDON | SINGAPORE | SYDNEY

CERTIFICATE OF ANALYSIS

Product Name : CELECOXIB CAPSULES 200MG	Date of Manufacture : JAN-2019
Batch Number : 970010	Expiry Date : FEB-2022
Batch Size : 750000 NO	Date Of Release : 30.03.2019
Pack Size : 50X10S	Importing Country : CHILE
Inspection Lot No. : 040000365738	Customer : PINNACLE LIFE
Specification No. : FG070092-00	SCIENCE PVT LTD

Address of manufacturer : Sy.No 11,12,13,14,15, Poojaramanahalli Village,
Bangalore Rural District - 562114

Sl. No.	TEST	SPECIFICATION	RESULT
01	DESCRIPTION	Hard gelatin capsule of size '2' with white opaque cap having a yellow band, and a white opaque body having a yellow band marked with '200' containing a white to off-white powder.	Hard gelatin capsule of size '2' with white opaque cap having a yellow band, and a white opaque body having a yellow band marked with '200' containing a off-white powder.
02	IDENTIFICATION*		Complies
	(i)By HPLC*	The retention time of the principal peak in the chromatogram of the test preparation should correspond to that of the standard preparation as obtained in assay.	The retention time of the principal peak in the chromatogram of the test preparation corresponded to that of the standard preparation as obtained in assay.
	(ii) By UV*	The absorption maxima of the test preparation should fall within ± 2 nm of the absorption maxima of the standard preparation	Complies
03	AVERAGE MASS OF FILLED CAPSULE*	333.0 mg $\pm$ 5.0% (316.4 mg to 349.7 mg)	328.8 mg
04	AVERAGE FILL MASS (NET CONTENT)*	270.0 mg $\pm$ 5.0%(256.5 mg to 283.5 mg)	262.7 mg
05	UNIFORMITY OF FILL MASS (NET CONTENT)*	Not more than 2/20 capsules shall deviate from the average fill mass by more than $\pm 10.0\%$ and no capsule shall deviate by more than $\pm 20.0\%$ of the average fill mass.	266.80-282.60 mg
	Minimum Uniformity Weight	$\pm 10 \%$	-3.3 %
	Maximum Uniformity Weight	$\pm 10 \%$	6.2 %

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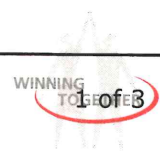


Regd. Off.: Medreich House, No. 12/8, Saraswati Ammal Street, Maruthi Sevanagar, Bangalore - 560 033, INDIA.

Phone: ++91 80 4048 7100 Fax: ++91 80 2547 4741

Factory: Sy. No. 11-15, Poojaramanahalli Village, Jadigenahalli Hobli, Old Madras Road, Hosakote Taluk,
Bangalore Rural District- 562 114, INDIA Phone: ++91 80 4048 7395 / 4048 7396

CIN : U24232KA1973PLC002383 E-mail: info@medreich.com, Website: www.medreich.com



CERTIFICATE OF ANALYSIS

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Address of manufacturer : Sy.No 11,12,13,14,15, Poojaramanahalli Village,
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Sl. No.	TEST	SPECIFICATION	RESULT
06	DISINTEGRATION TIME*	Not more than 30 minutes in water at 37°C ± 2°C.	4 Minutes 32 seconds
07	DISSOLUTION* [USP Type II (Paddle), 1000ml of pH 12 phosphate buffer + 1.0% SLS at 50 rpm] with sinkers.	Not less than 75% (Q) of the labeled amount of drug substance to be dissolved in 45 minutes.	93 - 100 %
08	UNIFORMITY OF DOSAGE UNITS (By mass variation)*	Acceptance value should meet the requirements of Ph. Eur. Chapter 2.9.40	L1=8.3 %
09	RELATED SUBSTANCES*		Complies
	Maximum single unknown impurity*	Not more than 0.1%	0.009 %
	Total Impurities*	Not more than 0.5%	0.020 %
10	ASSAY* Each hard gelatin capsule contains: Celecoxib Ph.Eur. Claim :200.0mg		
	In %*	95.0% to 105.0%	100.0 %
	In mg*	190.0mg to 210.0mg	200mg



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UNIT-VII
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Specification No.	: FG070092-00		

Address of manufacturer : Sy.No 11,12,13,14,15, Poojaramanahalli Village,
Bangalore Rural District - 562114

Sl. No.	TEST	SPECIFICATION	RESULT
11	MICROBIOLOGICAL LIMITS		Complies
	Total aerobic microbial count	Not more than 10^3 CFU/g	Less than 10cfu/g
	Total Yeasts and Moulds Count	Not more than 10^2 CFU/g	Less than 10cfu/g
	Bile-tolerant gram negative bacteria	Not more than 10^2 CFU/g	Less than 10cfu/g
	Salmonella	Absent/10g	Absent/10g
	Escherichia coli	Absent/g	Absent/g
	Staphylococcus aureus	Absent/g	Absent/g
12	WATER CONTENT*	For information only.	1.6%

The Product complies with the specification of FG070092-00

*Indicate Result from Bulk Stage

MANAGER – QUALITY CONTROL

DATE:

[Signature]
30/04/2019

MANAGER-QUALITY ASSURANCE

DATE:

[Signature]
30/04/2019



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