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CERTIFICATE OF ANALYSIS
(FINISHED-PACK)

Product: CELECOXIB 200 MG CAPSULES			
Batch No.	4B0172	**A.R. No.**	02FP19002301
Batch Size	70016.000 PAC	**Mfg. Date**	04/2019
Pack Size	1X10'S	**Exp. Date**	03/2022
Specification No.	FG01701745-01	**Product Code**	1701745
Inspection Lot. No.	040000381732	**Date Of Release**	01-08-2019 17:35

S. No.	TEST	RESULT	SPECIFICATION
1	**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 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 white to off-white powder.
2	**Identification**		
2.1	**a) By HPLC**	The retention time of the principle peak in the chromatogram of the test preparation correspond to that of the standard preparation as obtained in assay.	The retention time of the principle peak in the chromatogram of the test preparation should correspond to that of the standard preparation as obtained in assay.
2.2	**b) By UV**	The absorption maxima of the test preparation fall within ± 2 nm of the absorption maxima of the standard preparation.	The absorption maxima of the test preparation should fall within ± 2 nm of the absorption maxima of the standard preparation.
3	**Average mass of filled capsules**	329.9 mg	332.0 mg ± 5.0% (315.4 mg to 348.6 mg)
4	**Average fill mass (Net content)**	268.2 mg	270.0 mg ± 5.0% (256.5 mg to 283.5 mg)
5	**Uniformity of fill mass (Net content)**	Minimum:-4.0 % Maximum:5.2%	Not more than 2/20 capsules shall deviate from the average fill mass by more than ±10.0% and no capsule shall deviate by more than ±20.0% of the average fill mass.
6	**Disintegration time**	13.34 minutes	Not more than 30 minutes in water at 37°C ± 2°C.

Remarks: APPROVED (Sample Conforms to above Specification)

Approved By	Kumaresan.P (Senior Manager)	Authorized by	Dhas Prakash.A (Asst. Manager)
Approved On	01-08-2019 17:26	Authorized On	01-08-2019 17:35
Printed by: Dhas Prakash.A		Printed on: 05-08-2019 17:24	
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7	**Dissolution**	Minimum: 93.5 % Maximum: 99.1 % Average: 96.5 %	S1 Stage: Not less than 75% (Q) of the labeled amount of drug substance to be dissolved in 45 minutes.
8	**Uniformity of dosage units (By mass variation)**	8.8	Acceptance value should meet the requirements of Ph. Eur. chapter 2.9.40.
9	**Related substances**		
9.1	**Maximum single unknown impurity**	Not Detected	Not more than 0.1%
9.2	**Total impurities**	Not Detected	Not more than 0.7%
10	**Assay (Each hard gelatin capsule contains)**		
10.1	**Celecoxib Ph. Eur. (mg)**	192.8 mg	190.0mg to 210.0mg (Claim: 200.0 mg)
10.2	**Celecoxib (%)**	96.4 %	(95.0% to 105.0%)
11	**Water content**	2.35 %	For information only.

Test Plan Remarks: --

Remarks: APPROVED (Sample Conforms to above Specification)

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