

49 C & D, Bommasandra Industrial Area,
Anekal Taluk,
Bangalore-560099, Karnataka, India.



ANALYTICAL REPORT (RAW MATERIAL)

Material: CELECOXIB PH. EUR.

Manufacturer	AARTI DRUGS LIMITED (UNIT -II)	Received Qty	450.000 KG	Code	1102160
Supplier	AARTI DRUGS LIMITED (UNIT -II)	Received Date	20-11-2018	GRN No.	5000533190
Vendor Batch No.	CEB/18100060	A.R. No.	02RM18002721	Specification No.	R1102160-01
Mfg. Date	10/2018	Inventory Lot No.	D187001640	Sampling Date	21-11-2018
Exp. Date	09/2023	Inspection Lot No.	010000642249	Release Date	08-12-2018 12:32

S. No.	TEST	RESULT	SPECIFICATION
1	Appearance	White, crystalline powder	White or almost white, crystalline or amorphous powder
2	Solubility	Practically insoluble in water, freely soluble to soluble in anhydrous ethanol, soluble in methylene chloride.	Practically insoluble in water, freely soluble to soluble in anhydrous ethanol, soluble in methylene chloride.
3	Identification		
3.1	By IR	The IR absorption spectrum of sample concordant with the reference standard spectrum of Celecoxib WS.	The IR absorption spectrum of sample should be in concordant with the reference standard spectrum of Celecoxib CRS/WS.
4	Related substances		
4.1	Impurity A	0.0750 %	Not more than 0.4%
4.2	Impurity B	0.0120 %	Not more than 0.10%
4.3	Unspecified impurities	0.0800 %	Not more than 0.10%
4.4	Total impurities	0.1680 %	Not more than 0.5%
5	Water	0.24 %	Maximum 0.5%
6	Sulfated ash	0.11 %	Maximum 0.2%
7	Assay (By HPLC)	99.8 % w/w	98.0% to 102.0% w/w (anhydrous substance)
8	Additional tests		
8.1	Residual solvents (By GC)		
8.1.1	Methanol	34.05 ppm	Not more than 3000 ppm
8.1.2	Benzene	0.0 ppm	Not more than 1 ppm
8.1.3	Toluene	2.77 ppm	Not more than 890 ppm
9	Acetic acid content (By GC)	0.0 ppm	Not more than 1000 ppm
10	4-SPH Content (By HPLC)	0.0 %	Not more than 0.0002%
11	Melting point	160.2 °C	Between 159°C and 162°C
12	DSC	Complies	Two melting endotherms should observed at temperature about 161°C - 163°C
13	XRD	Complies	XRD pattern of test sample should match with XRD pattern of figure I of patent US

Remarks: APPROVED

Comment(s): --

Analysed By	Chenna kesavaiah.K (Officer)	Approved By	Shrishail.Atanur (Manager)
Analysed On	08-12-2018 10:45	Approved On	08-12-2018 12:32
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			2004/0087640A1)
14	Particle size (By Malvern)		
14.1	D₁₀	1 µm	Not more than 5 µm
14.2	D₅₀	6 µm	Between 5 to 20 µm
14.3	D₉₀	12 µm	Not more than 30 µm

Test Plan Remarks: --

Remarks: APPROVED

Comment(s): --

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