METAPHARMACEUTICAL

N DE LOTE: 0090724

10/07/2024

Aurore Life Sciences Pvt Ltd
Corporate Office: Plot # 68,69, 2d Floor, Jubilee Heights,
Beside Shilparamam, Madhapur, Hyderabad, Telangana 500081.
Ph: +91-40-2311321 1 Fax: 040-231 10044
E-mail: info@aurorels.com I Web: www.aurorels.com
CIN: U74999TG2016PTC112170

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Name of the Product	: CROMOLYN SODIUM (Ph. Eur)		
Batch No	: SKG3240003	Date of Analysis	: 20.06.2024
Batch Quantity	: 72.200 Kg	Analytical Report No	: AR/QCD/FP/06/24/0049
Manufacturing Date	: 06.05.2024	Dispatch quantity	: 50.00 Kg
Retest Date/~~Expiry Date~~	: 05.05.2026	No of unit packs	: NA
STP No.	: ASKG/STP/FP/003/00	Page No.	: 1 of 3
Customer Name and Country: Meta Pharmaceuticals and Spain.			

S. No.	TEST	RESULT	SPECIFICATIONS
1.0	Description	White hygroscopic crystalline powder	White or almost white, hygroscopic, crystalline powder.
2.0	Solubility	Complies	Soluble in water, practically insoluble in ethanol (96 percent).
3.0	**Identification by (Carry out either test 3.1, 3.2, 3.3,3.4)**		
3.1	IR	Complies	The absorption maxima, minima in the spectrum obtained with the sample shall be concordant in position relative intensity to those in the spectrum obtained to that of reference standard.
3.2	Reaction of Sodium	Complies	With potassium pyroantimonate solution it should show a dense white precipitate.
3.3	Test-C	Complies	With aminopyrazolone solution it should show an intense yellow color.

	Prepared by	Reviewed by	Approved by
Sign & Date	20/06/24	20/06/2024	
Name	Ch. Srinivas Reddy	P. Murali Reddy	K.P.V.V. Satyanarayana
Designation	Executive- QCD	Dy. Manager-QCD	Sr. Executive-QAD

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S. No.	TEST	RESULT	SPECIFICATIONS
3.4	Water content by KFR	6.85	Not more than 10.0%
4.0	Appearance of solution	Complies	2% solution is not more opalescent than reference suspension II, and not more intensely coloured than RS BY5
5.0	Acidity or alkalinity	Complies	Should comply
6.0	Related substance by HPLC (%,w/w)		
	Impurity-C	0.05	Not more than 0.3%
	Any unspecified impurity	0.04	Not more than 0.10%
	Total impurities	0.12	Not more than 0.35%
7.0	Test for Oxalate	Less than 0.35	Not more than 0.35%
8.0	Assay by HPLC (%,w/w) (On anhydrous basis)	99.8	Not less than 98.0% and not more than 101.0%
9.0	Residual solvents by HS-GC		
	Methanol	BDL (LOD=23 ppm)	Not more than 3000 ppm
	Ethanol	1271	Not more than 5000 ppm
	Acetone	Not Detected	Not more than 5000 ppm

	Prepared by	Reviewed by	Approved by
Sign & Date	20/06/24	20/06/2024	
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Customer Name and Country: Meta Pharmaceuticals and Spain.			

S. No.	TEST	RESULT	SPECIFICATIONS
	Isopropyl alcohol	Not Detected	Not more than 5000 ppm
	Toluene	BDL (LOD=10 ppm)	Not more than 890 ppm
10.0	Chloroform content by HS-GC		
	Chloroform	BDL (LOD=4 ppm)	Not more than 60 ppm

Storage condition : Store in airtight container, protected from light

Remarks : The Batch Complies to the Specification.

LOD: Limit of detection. **BDL:** Below detection limit.

	Prepared by	Reviewed by	Approved by
Sign & Date	20/06/24	20/06/2024	20/06/2024
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Aurore Life Sciences Pvt Ltd
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