METAPHARMACEUTICAL

N DE LOTE: 0090724





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

CIN: U/49991G2010P1C112170						
	C	ERTIFICATE O	F ANALYS	IS		
Name of the Product : CROMOLYN SODIUM (Ph. Eur)						
				of Analysis : 20.06.2024		
antity	: 72.200) Kg	The state of the s	Report No : AR/QCD/FP/06/24/0049		
turing Date			Dispatch quantity : 50.00 Kg			
ite/Expiry Date			No of unit packs : NA			
	AX 901770000000000000000			: 1 of 3		
r Name and Coun	try: Meta F			CONTROL TYONG		
TEST		RESUL	<u>.T</u>	SPECIFICATIONS		
		White hygroscopic		White or almost white,		
1.0 Description .		crystalline powder		hygroscopic, crystalline powder.		
2.0 Solubility		Complies		Soluble in water, practically		
				insoluble in ethanol (96 percent).		
Identification b	y (Carry	out either test 3.1,	3.2, 3.3,3.4			
	*	Complies		The absorption maxima, minima in		
				the spectrum obtained with the		
				sample shall be concordant in		
IR				position relative intensity to those		
				in the spectrum obtained to that of		
				reference standard.		
				With potassium pyroantimonate		
Reaction of Sodium		Complies		solution it should show a dense		
				white precipitate.		
		Complies		With aminopyrazolone solution it		
Test-C				should show an intense yellow		
				color.		
	the Product Diantity turing Date ate/Expiry Date TEST Description Solubility Identification b IR	the Product : CROM Signarity : 72.200 Entering Date : 06.05. Intering Date : 05.05. Intering Date : 05.05. Intering Date : 05.05. Intering Date : 05.05. Intering Date : 06.05. Interin	CERTIFICATE O The Product : CROMOLYN SODIUM of SKG3240003 Diantity : 72.200 Kg Turing Date : 06.05.2024 Date : 05.05.2026 ASKG/STP/FP/003/00 To Name and Country: Meta Pharmaceuticals and TEST RESULT Description Crystalline p Solubility Compliant Identification by (Carry out either test 3.1) Reaction of Sodium Compliant Reaction of Sodium Compliant Co	CERTIFICATE OF ANALYS The Product : CROMOLYN SODIUM (Ph. Eur) : SKG3240003 Date of An Analytical turing Date : 06.05.2024 Dispatch que (Expiry Date : 05.05.2026 No of unit : ASKG/STP/FP/003/00 Page No. or Name and Country: Meta Pharmaceuticals and Spain. TEST RESULT Description White hygroscopic crystalline powder Solubility Complies Identification by (Carry out either test 3.1, 3.2, 3.3,3.4) IR Complies Reaction of Sodium Complies		

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

ALS-SOP-QCD-016-AN001/01 (Effective Date:28.12.2021)

Aurore Life Sciences Pvt Ltd

Plot No. 180/2, 3, Khazipally (V), Jinnaram (M), Sangareddy (Dist.), Telangana. Pin Code: 502319.



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CIN: U74999TG2016PTC112170

7 200	QUA	LITY CONTROL	L DEPART	MENT	
	C	ERTIFICATE O	F ANALY:	SIS	
Name of	the Product : CROM	OLYN SODIUM	(Ph. Eur)		
Batch No	: SKG3	240003	0003 Date of Analysis : 20.06.2024		
Batch Qu	antity : 72.200) Kg	Analytical Report No : AR/QCD/FP/06		
Manufac	turing Date : 06.05.	2024	Dispatch o	*	
Retest Date/Expiry Date : 05.05.					
STP No.		G/STP/FP/003/00	Page No.	: 2 of 3	
Custome	r Name and Country: Meta F	Pharmaceuticals an	d Spain.		
S. No.	TEST	RESUL	T	SPECIFICATIONS	
3.4	Water content by KFR	6.85		Not more than 10.0%	
			8.	2% solution is not more opalescent	
		Complies		than reference suspension II, and	
4.0	Appearance of solution			not more intensely coloured than	
ā:	si s			20 000000000000000000000000000000000000	
				RS BY5	
5.0	Acidity or alkalinity C		es	Should comply	
6.0	Related substance by HPL	C (%,w/w)			
	Impurity-C	0.05		Not more than 0.3%	
	Any unspecified impurity	0.04		Not more than 0.10%	
	Total impurities			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)	99.8		Not less than 98.0% and not more	
	(On anhydrous basis)			than 101.0%	
9.0	Residual solvents by HS-C	A SECTION OF PRINCIPAL OF THE PRINCIPAL			
7.0	Methanol	BDL (LOD=23 ppm)		Not more than 3000 ppm	
	Ethanol	1271		Not more than 5000 ppm	
	to device the control of the control of	Not Dete			
	Acetone	Not Dete		Thot more than 5 000 pp.	

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

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Name of the Product

Batch No

STP No.

Batch Quantity

Manufacturing Date

Retest Date/Expiry Date

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E-mail: info@aurorels.com I Web: www.aurorels.com CIN: U74999TG2016PTC112170

: 3 of 3

QUALITY CONTR	OL DEPARTMENT	W
CERTIFICATI	E OF ANALYSIS	
: CROMOLYN SODIU	M (Ph. Eur)	×
: SKG3240003	Date of Analysis	: 20.06.2024
: 72.200 Kg	Analytical Report N	No: AR/QCD/FP/06/24/0049
: 06.05.2024	Dispatch quantity	: 50.00 Kg
: 05.05.2026	No of unit packs	: NA

Customer Name and Country: Meta Pharmaceuticals and Spain.

TEST	RESULT	SPECIFICATIONS
Isopropyl alcohol	Not Detected	Not more than 5000 ppm
Toluene	BDL (LOD=10 ppm)	Not more than 890 ppm
Chloroform content by I	HS-GC	
Chloroform	BDL (LOD=4 ppm)	Not more than 60 ppm
	Isopropyl alcohol Toluene Chloroform content by I	Isopropyl alcohol Not Detected Toluene BDL (LOD=10 ppm) Chloroform content by HS-GC

Storage condition

: Store in airtight container, protected from light

: ASKG/STP/FP/003/00 | Page No.

Remarks

: The Batch Complies to the Specification.

LOD: Limit of detection.

BDL: Below detection limit.

	Prepared by	Reviewed by	Approved by
Sign & Date	Quy 20 106 124	mural/2024	(Fran
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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