AZICO BIOPHORE

METAPHARMACEUTICAL

N DE LOTE: 0090224

Azico Biophore India Pvt. Ltd
425/3RT, Door No. 7-1-621/328
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTRC061809
+91-40-2381 0385 / 23705066
+91-40-2381 2709
info@Azicobiophore.com

07/02/2024

CERTIFICATE OF ANALYSIS

Product Name	**PROCAINAMIDE HYDROCHLORIDE**		
Reference	**Ph. Eur/In-House**	Mfg. Date	**27/08/2022**
Batch No.	**4028/3/001/22**	Expiry Date	**26/08/2027**
Date of Analysis	**28/06/2023**	Dispatch Qty.	**5.00 Kg**
Name of the Customer	**M/s. META PHARMACEUTICALS IND SL.**		

S. No.	Test Parameter	Specification	Result
1.	Description	White to very slightly yellow crystalline powder.	White crystalline Powder.
2.	Solubility		
	a) In Water	Very soluble in Water.	Complies
	b) In Methanol	Freely soluble in Methanol.	Complies
	c) In Acetone	Very slightly soluble in Acetone	Complies
3.	Identification by		
	A) IR Spectroscopy	The IR spectrum of the sample should match with the IR spectrum of the standard.	Complies
	B) HPLC	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that of the standard solution, as obtained in the assay by HPLC.	Complies
	C) Chloride	Sample solution yield a white, curdy precipitate with silver nitrate TS.	Complies
4.	pH	Between 5.6 and 6.3	5.88
5.	Melting range (°C)	Between 166 and 170	167.3 – 168.4
6.	Loss on drying (%,w/w)	Not more than 0.30	0.13
7.	Sulphated ash (%,w/w)	Not more than 0.10	0.06
8.	Appearance of Solution	Not more intensely colored than reference solution B6.	Complies
9.	Clarity of Solution	Solution should be clear	Complies

	Prepared By	Checked By	Approved By
Name	M. Saikumar	M. Sateesh	E. Nagabrahmam
Designation - Dept.	Chemist - QAD	Officer - QAD	Dy. Manager - QAD
Sign & Date	29/12/2023	29/12/23	29/12/23

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S. No.	Test Parameter	Specification	Result
10.	HCl content by Potentiometry (%,w/w on dried basis)	Between 12.1 and 14.8	13.4
11.	Related substances by HPLC (% w/w)		
	a) Highest individual unspecified impurity	Not more than 0.05	BDL
	b) Total impurities	Not more than 0.30	BDL
12.	Assay by HPLC (% w/w) (On dried basis)	Not less than 98.0 and Not more than 101.0	99.8
13.	Residual solvents by HS-GC (ppm)		
	a) N,N-Dimethyl formamide	Not more than 880	Not detected
	b) Toluene	Not more than 890	Not detected
	c) Dichloromethane	Not more than 600	Not detected
	d) Methanol	Not more than 3000	Not detected
	e) Ethyl acetate	Not more than 5000	Not detected
	f) Isopropyl alcohol	Not more than 5000	341

Chemical Name of Impurities:

Ortho isomer Impurity: 2-amino-N-(2-(diethylamino) ethyl) benzamide hydrochloride.

Packaging Conditions: Finished material shall be packed in transparent LDPE primary bag with nitrogen purging and tied with nylon strip then placed in black color LDPE secondary bag and tied with nylon strip then placed in triple laminated aluminum bag and seal with heat finally placed in HDPE container with clamp.

Storage conditions: Preserve in tight containers, protected from light. Store at 25°C, excursions permitted between 15°C and 30°C.

Remarks: The material Complies with the above specification.

Azico Biophore Anakapalli

	Prepared By	Checked By	Approved By
Name	M. Saikumar	M. Sateesh	E. Nagabrahmam
Designation - Dept.	Chemist - QAD	Officer - QAD	Dy. Manager - QAD
Sign & Date	29/12/2023	29/12/22	29/12/23

PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, ANAKAPALLI, A.P. INDIA