AZICO BIOPHORE

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

METAPHARMACEUTICAL

N DE LOTE: 0320224

29/02/2024.

CERTIFICATE OF ANALYSIS

Product Name	NADOLOL		
Reference	Ph. Eur.	Mfg. Date	09/06/2023
Batch No.	4016/3C/004/23	Expiry Date	08/06/2028
Date of Analysis	28/12/2023	Dispatch Qty	10.00 Kg.
Name of the Customer	M/s. Meta Pharmaceuticals		

S. No.	Test Parameter	Specification	Result
1.	Description	White or almost white, crystalline powder.	White crystalline powder.
2.	Solubility		
	a) In Ethanol	soluble in ethanol (96 per cent)	Complies
	b) In water	Slightly soluble in water at pH 8.0± 0.5	Complies
	c) In Acetone	Slightly soluble in Acetone	Complies
3.	Identification by		
	3.1 IR Spectroscopy	The IR spectrum of the sample should be match with that of standard spectrum.	Complies
	3.2 HPLC	The retention time of the major peak in chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay by HPLC.	Complies
4.	Loss on drying (%w/w) (at 60°C under vacuum for 3 hours)	Not more than 2.0	0.48
5.	Sulphated ash (%w/w)	Not more than 0.1	0.06
6.	Racemate composition by IR		
	Racemate A (%)	Between 40 and 60	56.4
7.	Related substances by HPLC (% w/w)		
	a) Impurity-A	Not more than 0.2	BRL
	b) Impurity-C	Not more than 0.2	0.08
	c) Impurity-D	Not more than 0.2	BRL

	Prepared By	Checked By	Approved By
Name	V. Ramateja	M. Sateesh	E. Naga Brahmam
Designation - Dept.	Chemist -QAD	Officer - QAD	Dy. Manager - QAD
Sign & Date	09/02/24	09/02/24	09/02/24

Azico Biophore India Pvt. Ltd. Anakapalli

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

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S. No.	Test Parameter	Specification	Result
	d) Highest individual Unspecified impurity	Not more than 0.10	BRL
	e) Total impurities	Not more than 0.5	0.08
8.	Assay by HPLC (%,w/w) (%,w/w On dried basis)	Not less than 98.0 and Not more than 102.0	99.8
9.	Assay by Potentiometry (%,w/w On dried basis)	Not less than 98.5 and Not more than 101.0	99.5
10.	Epichlorohydrin content by HS-GC (ppm)	Not more than 9	Not Detected
11.	Tertiary butyl amine content by HPLC (%,w/w)	Not more than 0.15	Not Detected
12.	Residual solvents by HS-GC (ppm)		
12.1	Method-I		
	a) Methanol	Not more than 3000	809
	b) Dichloromethane	Not more than 600	Not Detected
	c) Tertiary butanol	Not more than 208	Not Detected
	d) Triethyl amine	Not more than 320	BDL
	e) Toluene	Not more than 890	Not Detected
12.2	Method-II		
	Dimethyl Sulfoxide	Not more than 5000	Not Detected
12.3	Method-III		
	Acetone	Not more than 5000	1373

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Name of the Customer	**M/s. Meta Pharmaceuticals**		

Chemical Name of Impurities:

Impurity-A: Cis-5-[(2RS)-2, 3-dihydroxypropoxy]-1, 2, 3, 4-tetrahydronaphthalene-2, 3-diol (tetraol). (Tetraol/ Nadolol alcohol).

Impurity-C: 5,5'-[(2rs)-2-hydroxypropane-1,3-diylbis(oxy)]bis(cis-1,2,3,4-tetrahydro naphthalene-2,3-diol) (3 diastereoisomers/ Diaryl glycerol analog).

Impurity-D: 5,5'-[[1,1-dimethylethyl)imino]bis(2-hydroxypropane-1,3-diyl)oxy]]bis(cis-1,2,3,4-tetrahydronaphthalene-2,3-diol) (10 stereoisomers/ Nadolol dimer).

Packaging Conditions: Finished product shall be packed in transparent LDPE primary bag tied with nylon strip, followed by black LDPE bag which is tied with nylon strip, followed by triple laminated aluminum bag and hot seal then followed by HDPE container with clamp.

Storage Conditions: Preserve in well closed containers. Store at below 25°C. Excursions permitted between 15°C and 30°C.

Remarks: The material Complies as per the above specification.

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Sign & Date	09/02/24	09/02/24	09/02/2024

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