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: 0010124

03/01/2024.

CERTIFICATE OF ANALYSIS

Product Name	NADOLOL USP		
Reference	USP	Mfg. Date	09/06/2023
Batch No.	4016/3C/004/23	Expiry Date	08/06/2028
Date of Analysis	19/06/2023	Dispatch Qty.	20.00 kg.
Name of the Customer	M/s. METAPHARMACEUTICAL IND SL.		

S. No.	Test Parameter	Specification	Result
1.	Description	White to off-white, practically odorless, crystalline powder.	White crystalline Powder
2.	Solubility		
	a) In Methanol	Freely soluble in Methanol	Complies
	b) In Water	Soluble in water at pH 2	Complies
	c) In alcohol	Soluble in alcohol	Complies
	d) In Isopropyl alcohol	Slightly soluble in Isopropyl alcohol	Complies
	e) In Water at pH 8.0±0.5	Slightly soluble in water at pH 8.0± 0.5	Complies
3.	Identification by		
	3.1 IR Spectroscopy	The IR spectrum of the sample should be match with that of standard.	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.	Residue on ignition (%w/w)	Not more than 0.10	0.06
6.	Racemate composition by IR		
	Racemate A (%)	Between 40 and 60	56.4
7.	Related substances by HPLC (% w/w)		
	a) Nadolol alcohol (Impurity-A)	Not more than 0.20	0.09
	b) Nadolol Methoxy analog (Impurity-B)	Not more than 0.20	Not detected

Azico Biophore India Pvt. Ltd. Anakapalli

	Prepared By	Checked By	Approved By
Name	M. Saikumar	E. Naga Brahmam	Adapa. V. Uma Phani
Designation - Dept.	Chemist - QAD	Dy. Manager - QAD	Dy. Manager - QAD
Sign & Date	22/11/2023	22/11/23	22/11/23

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S. No.	Test Parameter	Specification	Result
	c) Nadolol dimer (Impurity-C)	Not more than 0.20	BQL
	d) Diaryl glycerol analog (Impurity-D)	Not more than 0.20	0.05
	e) Napthyl analog (Impurity-E)	Not more than 0.20	Not detected
	f) Dideoxy Nadolol (Impurity-F)	Not more than 0.20	Not detected
	g) Single maximum Unknown impurity	Not more than 0.10	BDL
	h) Total impurities	Not more than 0.50	0.14
8.	Assay by HPLC (%w/w) (On dried basis)	Not less than 98.0 and Not more than 102.0	99.8
9.	Epichlorohydrin content by HS-GC (ppm)	Not more than 9	Not detected
10.	Tertiary butyl amine content by HPLC (%w/w)	Not more than 0.15	Not detected
11.	Residual solvents by HS-GC (ppm)		
	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
	Method-II		
	Dimethyl sulfoxide	Not more than 5000	Not detected
	Method-III		
	Acetone	Not more than 5000	1373

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Chemical Name of Impurities:

Specified impurities:

Nadolol alcohol (Impurity-A): (2RS, 3SR)-5-(2,3-Dihydroxypropoxy)-1,2,3,4-tetrahydronaphthalene-2,3-diol.

Nadolol Methoxy analog (Impurity-B): (2RS,3SR)-5-(2-Hydroxy-3-methoxypropoxy)-1,2,3,4-tetrahydronaphthalene-2,3-diol)

Nadolol dimer (Impurity-C): (2SR,3RS)-5-[3-[tert-Butyl (3-[(6RS,7SR)-6,7-dihydroxy-5,6,7,8-tetrahydronapthalen-1-yl]oxy]-2hydroxypropyl)amino]-2-hydroxypropoxy]-1,2,3,4-tetrahydronaphthalene-2,3-diol..

Diaryl glycerol analog (Impurity-D): (2SR,3RS)-5-(3-[[(6RS,7SR)-6,7-dihydroxy-5,6,7,8-tetrahydronapthalene-1-yl]oxy]-2-hydroxypropoxy)-1,2,3,4- tetrahydronapthalene -2,3-diol and 1,3-Bis[(6R,7S)-6,7-dihydroxy-5,6,7,8- tetrahydronapthalene-1-ylox-y]propane-2-ol.

Napthyl analog (Impurity-E): 1-(tert-Butylamino)-3-(naphthalene-1-yloxy)propan-2-ol.

Dideoxy Nadolol (Impurity-F): 1-(tert-Butylamino)-3-(5,6,7,8-tertahydronaphthalen-1-yloxy)propan-2-ol.

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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