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

CERTIFICATE OF ANALYSIS

Product Name	**NADOLOL USP**		
Reference	**USP**	Mfg. Date	**08/09/2020**
Batch No.	**4016/3/002/20**	Retest Date	**07/09/2023**
Date of Analysis	**14/09/2020**	Dispatch Qty	---
Name of the Customer	---		

S. No.	Test Parameter	Specification	Result
1.	Description	White to off-white, crystalline powder.	White Crystalline powder
2.	Solubility		
	a) In Methanol	Freely soluble in Methanol	Complies
	b) In Water at pH 2.0	Soluble in water at pH 2.0	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 corresponds 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	0.14
5.	Residue on ignition (%w/w)	Not more than 0.10	0.02
6.	Racemate composition by IR		
	Racemate A (%)	Between 40 and 60	50.2
7.	Related substances by HPLC (% w/w)		
	a) Nadolol alcohol (Impurity-A)	Not more than 0.20	Not detected
	b) Nadolol Methoxy analog (Impurity-B)	Not more than 0.20	Not detected
	c) Nadolol dimer (Impurity-C)	Not more than 0.20	Not detected

	Prepared By	Checked By	Approved By
Name	V. Satish	M.V. Uma Phani	B. Naga Prasad
Designation & Dept.	Sr. Chemist -QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	05/12/2020	05/12/2020	05/12/2020

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S. No.	Test Parameter	Specification	Result
	d) Diaryl glycerol analog (Impurity-D)	Not more than 0.20	Not detected
	e) Napthyl analog (Impurity-E)	Not more than 0.20	BQL
	f) Dideoxy Nadolol (Impurity-F)	Not more than 0.20	Not detected
	g) Highest individual unspecified impurity	Not more than 0.10	BDL
	h) Total impurities	Not more than 0.50	BQL
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	0.01
11.	Residual solvents by HS-GC (ppm)		
	Method-I		
	a) Methanol	Not more than 3000	674
	b) Dichloromethane	Not more than 600	Not detected
	c) Tertiary butanol	Not more than 208	Not detected
	d) Triethyl amine	Not more than 320	Not detected
	e) Toluene	Not more than 890	BDL
	Method-II		
	Dimethyl sulfoxide	Not more than 5000	Not detected
	Method-III		
	Acetone	Not more than 5000	99

Chemical Name of Impurities:

Specified impurities:

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

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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.

	Prepared By	Checked By	Approved By
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Sign & Date	V. Satish 05/12/2020	05/12/2020	05/12/2020