

Approved By / Date

Quality Assurance

AMRI India Pvt. Ltd., Plot No.: G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, Maharashtra, India, t: +91-240-2554006 / 2564456 | www.amriglobal.com

		QUALITY CONTROL CERTIFICATE O	L DEPA	RTMENT	
Type	: Dispatch			The state of the s	
Prod	uct Name: ATENOLOL		Page: 1 of 2		
	pendia: EP		Batch Number: AM20112189		
Mfg. Date: OCT -2012			Quantity: 250 Kg.		
Date of Sampling: 29/10/2012			Exp. Date: SEP-2017 Date of Analysis: 29/10/2012		
D 4 cD 1			A.R Number: FPA/12/240		
100000					
	ge Condition :- Protect f		nperatur	e not exceeding 25°C	
S.No. 1.	~ 000	Results		Specification	
2.	Description	Almost white powder		A white or almost white powder	
2.	Solubility	Complies		Soluble in anhydrous Ethanol, sparingly	
				soluble in water, slightly soluble in	
3.	Identification			methylene chloride. Soluble in Ethanol.	
٥,				First Identification C	
	A) By Melting Point	154°C		Second Identification A, B, D.	
	B) By UV	1.16		152°C to 155°C	
		1.16		1.15 to 1.20	
	C) By IR	Complies		Should be comparable with Atenolol	
		•		working standard.	
	D) By TLC	Complies		Should be comparable with Atenolol	
	, i	•		working standard.	
	Appearance of solution	1.0% w/v solution in water is		1.0%w/v solution in water should be	
4.		clear & transparent		clear & not more intensely colored than	
				degree 6 of the range of reference	
-	0 : 15			solutions of the most appropriate color.	
5.	Optical Rotation	0°		+0.10° to -0.10°	
6.	Chlorides	Less than 0.1%		NMT 0.1%	

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09/11/12



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QUALITY	Y CONTROL DEPARTMENT
CERT	TIFICATE OF ANALYSIS
Type: Dispatch	Page: 2 of 2
Product Name: ATENOLOL Compendia: EP	Batch Number: AM20112189
	Quantity: 250 Kg.
Mfg. Date: OCT -2012	Exp. Date: SEP-2017
Date of Sampling: 29/10/2012	Date of Analysis: 29/10/2012
Date of Release: 31/10/2012	A.R Number: FPA/12/240

S.No.	Test	Results	Specification	
7.	Related Substances		Specification	
	Impurity B	0.09%	NMT 0.20%	
	Impurities F	0.09%	NMT 0.15%	
	Impurities G	0.05%	NMT 0.15%	
	Impurities I	Less than 0.05%	NMT 0.15%	
	Unspecified Impurities	Less than 0.05%	NMT 0.10%	
	Total Impurity	0.34 %	NMT 0.5%	
8.	Sulphated Ash	0.05%	NMT 0.1%	
9.	Loss on drying	0.27%	NMT 0.5% w/w	
10.	Assay (ODB) Potentiometer	99.46%	99.0% to 101.0% w/w	
11.	Foreign Particle	No black Particles observed on filter paper	butteres observed on	
12.	Aditional Tests	Ton Inter paper	filter paper	
1.	* Bulk Density			
	Untapped Tapped (50 strokes)	0.26 gm/mL 0.36 gm/mL	Informative	
2.	Particle Size	100% sample passes through 40 mesh	100% passing through 40 mesh.	

^{*}Bulk density determined as per in-house requirement.

• Remarks:- The product Complies as per EP specification

We certify that the material manufactured in our factory, address- AMRI India Pvt. Ltd. G-1/1, MIDC, Aurangabad is as per process described in the certificate of suitability. We also certify that the quality of the material complies according to the certificate of suitability (No: R1-CEP 1999-122-Rev 04) of the monographs of the European Pharmacopoeia.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
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