

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 DEPARTMENT CERTIFICATE OF ANALYSIS			
Product Name: ATENOLOL	Batch Number: AM20113030		
Compendia: EP	Quantity: 175 Kg.		
Mfg. Date: FEB -2013	Retest Date: JAN-2018		
Date of Sampling: 23/02/2013	Date of Analysis: 23/02/2013		
Date of Release: 02/03/2013	A.R Number: FPA/13/038		

**Storage Condition** :- Protect from light and store at temperature not exceeding 25°C

S.No.	Test	Results	Specification	
1.	Description	Almost white powder	A white or almost white powder	
2.	Solubility	Complies	Soluble in anhydrous Ethanol, sparingly	
	Transfer of	9.00%	soluble in water, slightly soluble in methylene chloride.	
3.	Identification		First Identification C	
	A) By Melting Point	154°C	Second Identification A, B, D.	
			152°C to 155°C	
	B) By UV	1.15	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 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	
			solutions of the most appropriate color.	
5.	Optical Rotation	0°	+0.10° to - 0.10°	
6.	Chlorides	Less than 0.1%	NMT 0.1%	

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Cogas Joyhors	2004/2013	23/04/2013	72AS 23/04/2013
Quality Control	Quality Control	Quality Assurance	Quality Assurance



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S.No.	Test	Results	Specification
7.	Related Substances		
	Impurity B	0.05%	NMT 0.20%
	Impurities F	0.05%	NMT 0.15%
	Impurities G	Less than 0.05%	NMT 0.15%
	Impurities I	Less than 0.05%	NMT 0.15%
	Unspecified Impurities	0.06%	NMT 0.10%
- 15	Total Impurity	0.24 %	NMT 0.5%
8.	Sulphated Ash	0.07%	NMT 0.1%
9.	Loss on drying	0.31%	NMT 0.5% w/w
10.	Assay (ODB) Potentiometer	99.57%	99.0% to 101.0% w/w
11.	Foreign Particle	No black Particles observed on filter paper	NMT 5 black particles observed on filter paper
12.	Additional Tests		popul
1.	* Bulk Density		
	1) Untapped	0.27` gm/mL	Informative
	2) Tapped (50 strokes)	0.37 gm/mL	
2.	Particle Size	100% sample passes through 40 mesh	100% passing through 40 mesh.

<sup>\*</sup>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
23/04/2012	23/04/23	23/04/2013	72AV 23/04/2013
Quality Control	Quality Control	Quality Assurance	Quality Assurance