

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

		QUALITY CONTROL D CERTIFICATE OF A	EPARTMENT		
Type	: Dispatch				
Prod	uct Name: ATENOLOL		Page: 1 of 2		
Com	pendia: EP	Bato	Batch Number: AM20112188		
Mfg.	Date: OCT -2012	Qua	Quantity: 150 Kg.		
Date	of Sampling: 28/10/2012	Exp	Exp. Date: SEP-2017		
Date	of Release: 30/10/2012	12000	Date of Analysis: 28/10/2012		
		A.R	A.R Number: FPA/12/239		
Stora	ge Condition :- Protect f	from light and store at tempe	rature 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		
			soluble in water, slightly soluble in		
			methylene chloride. Soluble in Ethanol.		
3.	Identification		First Identification C		
	A) By Melting Point	154°C	Second Identification A, B, D.		
			152°C to 155°C		
	B) By UV	1.16	1.15 to 1.20		
	C/D-ID		112 10 1.20		
	C) By IR	Complies	Should be comparable with Atenolol		
	D) D TOY C		working standard.		
	D) By TLC	Complies	Should be comparable with Atenolol		
			working standard		
	Appearance of solution	Will borderous all water	r 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		
_		<i>t</i>	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
Ent ogmile	Joseph comment	#mother E	Kghahane 09/11/120/2
Quality Control	Quality Control	Quality Assurance	Quality Assurance



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QUALITY	Y CONTROL DEPARTMENT
CERT	TIFICATE OF ANALYSIS
Type: Dispatch	Page: 2 of 2
Product Name: ATENOLOL	Batch Number: AM20112188
Compendia: EP	Quantity: 150 Kg.
Mfg. Date: OCT -2012	Exp. Date: SEP-2017
Date of Sampling: 28/10/2012	Date of Analysis: 28/10/2012
Date of Release: 30/10/2012	A.R Number: FPA/12/239

S.No.	Test	Results	Specification		
7.	Related Substances				
	Impurity B	0.09%	NMT 0.20%		
	Impurities F	0.07%	NMT 0.15%		
	Impurities G	Less than 0.05%	NMT 0.15%		
	Impurities I	Less than 0.05%	NMT 0.15%		
	Unspecified Impurities	0.05%	NMT 0.10%		
	Total Impurity	0.29 %	NMT 0.5%		
8.	Sulphated Ash	0.08%	NMT 0.1%		
9.	Loss on drying	0.30%	NMT 0.5% w/w		
10.	Assay (ODB). Potentiometer	99.52%	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.	Aditional Tests				
1.	* Bulk Density				
	1) Untapped	0.26 gm/mL	Informative		
	2) Tapped (50 strokes)	0.36 gm/mL			
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 Pharmacopocia.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
CENT OPHINE	1 October	Og/11/2012	Shahane 09/11/2012
Quality Control	Quality Control	Quality Assurance	Quality Assurance