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

Type: Dispatch	**Page:** 1 of 2
Product Name: ATENOLOL	**Batch Number:** AM20112190
Compendia: EP	**Quantity:** 250 Kg.
Mfg. Date: OCT -2012	**Exp. Date:** SEP-2017
Date of Sampling: 31/10/2012	**Date of Analysis:** 31/10/2012
Date of Release: 05/11/2012	**A.R Number:** FPA/12/241

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 soluble in water, slightly soluble in methylene chloride. Soluble in Ethanol.
3.	Identification A) By Melting Point	154°C	First Identification C Second Identification A, B, D. 152°C to 155°C
	B) By UV	1.17	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.
4.	Appearance of solution	1.0% w/v solution in water is clear & transparent	1.0%w/v solution in water should be 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
09/11/12	09/11/2012	09/11/2012	09/11/2012
Quality Control	Quality Control	Quality Assurance	Quality Assurance

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S.No.	Test	Results	Specification
7.	Related Substances		
	Impurity B	0.11%	NMT 0.20%
	Impurities F	0.09%	NMT 0.15%
	Impurities G	Less than 0.05%	NMT 0.15%
	Impurities I	0.06%	NMT 0.15%
	Unspecified Impurities	Less than 0.05%	NMT 0.10%
	Total Impurity	0.34 %	NMT 0.5%
8.	Sulphated Ash	0.08%	NMT 0.1%
9.	Loss on drying	0.26%	NMT 0.5% w/w
10.	Assay (ODB) Potentiometer	99.62%	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 2) Tapped (50 strokes)	 0.26 gm/mL 0.35 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
09/11/12	09/11/2012	09/11/2012	09/11/2012
Quality Control	Quality Control	Quality Assurance	Quality Assurance