AMRI India Pvt. Ltd. G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, India.
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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Type: Dispatch	**Page:** 1 of 2
Product Name: ATENOLOL	**Batch Number:** AM20114008
Compendia: EP	**Quantity:** 250 Kg.
Mfg. Date: JAN -2014	**Retest Date:** DEC-2018
Date of Sampling: 08/02/2014	**Date of Analysis:** 08/02/2014
Date of Release: 14/02/2014	**A.R Number:** FPA/14/008

Storage Condition :- Preserve in well-closed, light resistant container. Store at 25°C, excursions permitted between 15°C to 30°C

S.No.	Test	Results	Specification
1.	Appearance	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.
3.	Identification A) By Melting Point	154.8°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 Rotations	0°	+0.10° to – 0.10°
6.	Chloride	Less than 0.1%	NMT 0.1%

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
14/02/2014	14/02/2014	14/02/2014	14/2/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance

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S.No.	Test	Results	Specification
7.	Related Substances By HPLC		
	Impurity B	0.13%	NMT 0.20%
	Impurity F	BDRL	NMT 0.15%
	Impurity G	0.08%	NMT 0.15%
	Impurity I	0.05%	NMT 0.15%
	Unspecified Impurity	0.09%	NMT 0.10%
	Total Impurities	0.41 %	NMT 0.5%
8.	Sulphated Ash	0.07%	NMT 0.1%
9.	Loss on drying	0.24%	NMT 0.5% w/w
10.	Assay (ODB) by Potentiometer	99.82%	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		
12.1	Bulk Density 1) Untapped 2) Tapped (50 strokes)	 0.24 gm/mL 0.31 gm/mL	Informative
12.2	Particle Size	100% sample passes through 40 mesh	100% passing through 40 mesh.

*Additional test determined as per in-house requirement.

- **BDRL** – Below Disregard Limit (Disregard Limit is 0.05% as per EP 7.0)
- **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
14/02/2014	14/02/2014	14/02/2014	14/02/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance