



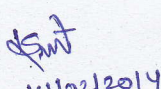
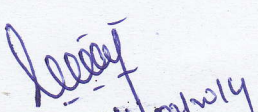
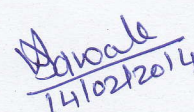
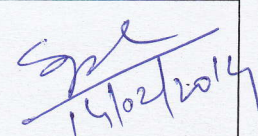
AMRI India Pvt. Ltd. G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, India.
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QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Type: Dispatch	Page: 1 of 2
Product Name: ATENOLOL	Batch Number: AM20114007
Compendia: EP	Quantity: 225 Kg.
Mfg. Date: JAN -2014	Retest Date: DEC-2018
Date of Sampling: 04/02/2014	Date of Analysis: 04/02/2014
Date of Release: 10/02/2014	A.R Number: FPA/14/007

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	154.6°C	First Identification C Second Identification A, B, D. 152°C to 155°C
	B) By UV	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 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	 14/02/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance



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S.No.	Test	Results	Specification
7.	Related Substances By HPLC Impurity B Impurity F Impurity G Impurity I Unspecified Impurity Total Impurities	0.08% 0.06% 0.07% 0.07% 0.08% 0.38 %	NMT 0.20% NMT 0.15% NMT 0.15% NMT 0.15% NMT 0.10% NMT 0.5%
8.	Sulphated Ash	0.05%	NMT 0.1%
9.	Loss on drying	0.22%	NMT 0.5% w/w
10.	Assay (ODB) by 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		
12.1	Bulk Density 1) Untapped 2) Tapped (50 strokes)	0.23 gm/mL 0.30 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.

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 14/02/2014	 14/02/2014	 14/02/2014	 14/02/2014
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