



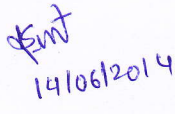

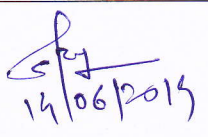
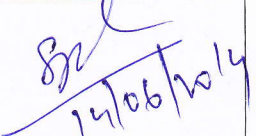
AMRI India Private Limited, Plot No. G-1/1, 1/2, MIDC Area, Waluj, Aurangabad-431 136, India  
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**QUALITY CONTROL DEPARTMENT**  
**CERTIFICATE OF ANALYSIS**

<b>Type:</b> Dispatch	<b>Page:</b> 1 of 2
<b>Product Name:</b> ATENOLOL	<b>Batch Number:</b> AM20114041
<b>Compendia:</b> EP	<b>Quantity:</b> 225 Kg.
<b>Mfg. Date:</b> MAY -2014	<b>Retest Date:</b> APR-2019
<b>Date of Sampling:</b> 27/05/2014	<b>Date of Analysis:</b> 27/05/2014
<b>Date of Release:</b> 31/05/2014	<b>A.R Number:</b> FPA/14/045

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

Sr.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	153.3 °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
 14/06/2014	 14/06/2014	 14/06/2014	 14/06/2014
Quality Control	Quality Control	Quality Assurance	Quality Assurance





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Sr.No.	Test	Results	Specification
7.	Related Substances By HPLC Impurity B Impurity F Impurity G Impurity I Unspecified Impurity Total Impurities	0.16 % BDRL 0.08 % 0.11 % 0.09 % 0.46 %	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	0.28 % w/w	NMT 0.5 % w/w
10.	Assay (ODB) by Potentiometer	100.24 % w/w	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
 14/06/2014	 14/06/2014	 14/06/2014	 14/06/2014
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