

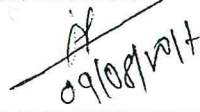
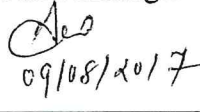
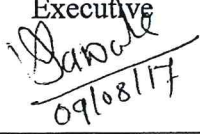
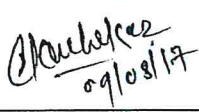


Format No. QCD/021/F.01.02

AMRI, India Pvt. Ltd. | G-1/1, MIDC Area, Waluj, Aurangabad-431 136, India
t. +91-240-2554006 | 2564456 | www.amriglobal.com

CERTIFICATE OF ANALYSIS

Product Name: ATENOLOL		Batch Number: AM20315017	
Compendia: EP		Batch Quantity: 375.15 kg	
Mfg. Date: 26-Sep-2015		Retest Date: 25-Sep-2020	
Date of Analysis: 01/10/2015		Date of Release: 27/06/2017	
A.R Number: FP/15/0069		Page 1 of 2	
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 First Identification C Second Identification A, B, D.		
	A) By Melting Point	NA	152°C to 155°C
	B) By UV	NA	1.15 to 1.20
	C) By IR	Complies	Should be comparable with Atenolol working standard.
	D) By TLC	NA	Should be comparable with Atenolol working standard.
4.	Appearance of solution	Complies	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	+0.023°	+0.10° to – 0.10°
6.	Chloride	Less than 0.1%	NMT 0.1%
7.	Related Substances By HPLC		
	Impurity B	0.09 %	NMT 0.2%
	Impurity F	BDL	NMT 0.15%
	Impurity G	BQL	NMT 0.15%
	Impurity I	BQL	NMT 0.15%
	Impurity J	0.05%	NMT 0.15%
	Unspecified Impurity	BDL	NMT 0.10%
	Total Impurities	0.14 %	NMT 0.5%

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Santosh Patil Sr. Executive  09/08/2017	Arjun Gapat Asst. Manager  09/08/2017	Sachin Jawale Executive  09/08/17	Sudhan Kuchekar Sr. Executive  09/08/17
Quality Control	Quality Control	Quality Assurance	Quality Assurance



Format No. QCD/021/F.01.02

AMRI, India Pvt. Ltd. | G-1/1, MIDC Area, Waluj, Aurangabad-431 136, India
t. +91-240-2554006 | 2564456 | www.amriglobal.com

CERTIFICATE OF ANALYSIS

Product Name: ATENOLOL		Batch Number: AM20315017	
Compendia: EP		Batch Quantity: 375.15 kg	
Mfg. Date: 26-Sep-2015		Retest Date: 25-Sep-2020	
Date of Analysis: 01/10/2015		Date of Release: 27/06/2017	
A.R Number: FP/15/0069		Page 2 of 2	
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

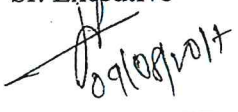
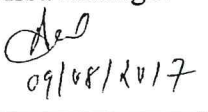
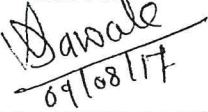
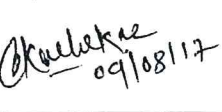
8.	Sulphated Ash	0.07 % w/w	NMT 0.1%
9.	Loss on drying	0.19 % w/w	NMT 0.5% w/w
10.	Assay (ODB) by Potentiometer	100.5 % w/w	99.0% to 101.0% w/w
11.	Foreign Particle	Complies	NMT 5 black particles observed on filter paper
*Additional Tests			
12.	Bulk Density 1) Untapped 2) Tapped (50 strokes)	0.25 gm/mL 0.31 gm/mL	Informative Informative
13.	Particle Size (By sieve method)	Complies	100% passing through 40 mesh.

*Additional tests determined as per in-house requirement.

If Identification test by IR has been done then there is no need to perform by second identification tests.

- **BQL** – Below Quantification Limit (Quantification Limit is 0.05%)
- **BDL** – Below Detection Limit (Detection Limit is 0.02%)
- **NA** – Not Applicable.
- **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, 1/2, MIDC, Waluj, 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 (COS No.: R1-CEP 1999-122-REV 06) of the monographs of the European Pharmacopoeia.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
Santosh Patil Sr. Executive 	Arjun Gapat Asst. Manager 	Sachin Jawale Executive 	Sudhan Kuchekar Sr. Executive 
Quality Control	Quality Control	Quality Assurance	Quality Assurance