

AMRI India Pvt. Ltd. G - 1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, India. t: +91-240-2554006 / 2564456, www.amriglobal.com

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.

 $+0.10^{\circ}$ to -0.10°

NMT 0.1%

		QUALITY CONTR	OL DEPA	RTMENT	
		CERTIFICATE			
Type: Dispatch			Page: 1 of 2		
			Batch Number: AM20113066		
Compendia: EP			Quantity: 250 Kg.		
Mfg. Date: APR -2013			Retest Date: MAR-2018		
Date of Sampling: 29/04/2013			Date of Analysis: 29/04/2013		
Date o	Date of Release: 30/04/2013			A.R Number: FPA/13/074	
Storag	ge Condition :- Protect f	from light and store at	temperatur	e not exceeding 25°C	
S.No.	Test	Results		Specification	
1.	Appearance	Almost white power	ler	A white or almost white powder	
2.	Solubility	Complies		Soluble in anhydrous ethanol, sparingly	
				soluble in water, slightly soluble in	
				methylene chloride.	
3.	Identification	1005775		First Identification C	
	A) By Melting Point	152°C		Second Identification A, B, D.	
				152°C to 155°C	
	B) By UV	1.19		1.15 to 1.20	
	C) By IR	Complies		Should be comparable with Atenolol	
		100 1014		working standard.	
	D) By TLC	Complies		Should be comparable with Atenolol	
	Pure on Paranta	Law book Rained		working standard.	

1.0% w/v solution in water is

clear & transparent

Less than 0.1%

Appearance of solution

Optical Rotation

Chlorides

4.

5.

Prepared By /Date	Checked By / Date	Reviewed By / Date	Approved By / Date
27/08/2013	10000 2710811013	27/08/2013	Kohahame - 20/08/20/3
Quality Control	Quality Control	Quality Assurance	Quality Assurance



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QUALITY	CONTROL DEPARTMENT	
CERT	IFICATE OF ANALYSIS	
Type: Dispatch	Page: 2 of 2	
Product Name: ATENOLOL	Batch Number: AM20113066	
Compendia: EP	Quantity: 250 Kg.	
Mfg. Date: APR -2013	Retest Date: MAR-2018	
Date of Sampling: 29/04/2013	Date of Analysis: 29/04/2013	
Date of Release: 30/04/2013	A.R Number: FPA/13/074	

S.No.	Test	Results	Specification
7.	Related Substances		
	Impurity B	0.08%	NMT 0.20%
	Impurities F	0.06%	NMT 0.15%
	Impurities G	Less than 0.05%	NMT 0.15%
	Impurities I	0.07%	NMT 0.15%
	Unspecified Impurities	Less than 0.05%	NMT 0.10%
	Total Impurity	0.29 %	NMT 0.5%
8.	Sulphated Ash	0.06%	NMT 0.1%
9.	Loss on drying	0.30%	NMT 0.5% w/w
10.	Assay (ODB) by Potentiometer	99.18%	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		
5	1) Untapped	0.26 gm/mL	Informative
	2) Tapped (50 strokes)	0.37 gm/mL	
12.2	Particle Size	100% sample passes 100% passing through 40 mesh. through 40 mesh	

^{*}Additional test 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
27/08/2013	Joseph 13	27/08/2013	Krhahane 25/08/2013
Quality Control	Quality Control	Quality Assurance	Quality Assurance