**AMRI**

AMRI India Pvt. Ltd.,  
Plot No.: G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, Maharashtra, India,  
t: +91-240-2554006 / 2564456 | www.amriglobal.com

**QUALITY CONTROL DEPARTMENT  
CERTIFICATE OF ANALYSIS**

Type: Dispatch

Product Name: ATENOLOL

Compendia: EP

Mfg. Date: SEP -2012

Date of Sampling: 30/09/2012

Date of Release: 02/10/2012

Page: 1 of 2

Batch Number: AM20112169

Quantity: 200 Kg.

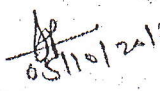
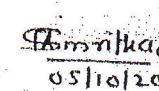
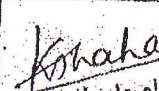
Exp. Date: AUG-2017

Date of Analysis: 02/10/2012

A.R Number: FPA/12/220

Storage Condition :- Protect from light and store at temperature not exceeding 25°C

| S.No. | Test                   | Results                                           | Specification                                                                                                                                           |
|-------|------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.    | Description            | 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. Soluble in Ethanol.                                   |
| 3.    | Identification         |                                                   | First Identification C                                                                                                                                  |
|       | A) By Melting Point    | 155°C                                             | Second Identification A, B, D.<br>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 Rotation       | 0°                                                | +0.10° to - 0.10°.                                                                                                                                      |
| 6.    | Chlorides              | Less than 0.1%                                    | NMT 0.1%                                                                                                                                                |

| Prepared By / Date                                                                                | Checked By / Date                                                                                 | Reviewed By / Date                                                                                | Approved By / Date                                                                                  |
|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <br>05/10/2012 | <br>05/10/2012 | <br>05/10/2012 | <br>05/10/2012 |
| Quality Control                                                                                   | Quality Control                                                                                   | Quality Assurance                                                                                 | Quality Assurance                                                                                   |



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AMRI India Pvt. Ltd.,

**QUALITY CONTROL DEPARTMENT**  
**CERTIFICATE OF ANALYSIS**

|                              |                              |
|------------------------------|------------------------------|
| Type: Dispatch               | Page: 2 of 2                 |
| Product Name: ATENOLOL       | Batch Number: AM20112169     |
| Compendia: EP                | Quantity: 200 Kg.            |
| Mfg. Date: SEP -2012         | Exp. Date: AUG-2017          |
| Date of Sampling: 30/09/2012 | Date of Analysis: 02/10/2012 |
| Date of Release: 02/10/2012  | A.R Number: FPA/12/220       |

| S.No. | Test                                                    | Results                                     | Specification                                  |
|-------|---------------------------------------------------------|---------------------------------------------|------------------------------------------------|
| 7.    | Related Substances                                      |                                             |                                                |
|       | Impurity B                                              | 0.08%                                       | NMT 0.20%                                      |
|       | Impurities F                                            | Less than 0.05%                             | NMT 0.15%                                      |
|       | Impurities G                                            | Less than 0.05%                             | NMT 0.15%                                      |
|       | Impurities I                                            | Less than 0.05%                             | NMT 0.15%                                      |
|       | Unspecified Impurities                                  | Less than 0.05%                             | NMT 0.10%                                      |
|       | Total Impurity                                          | 0.21 %                                      | NMT 0.5%                                       |
| 8.    | Sulphated Ash                                           | 0.07%                                       | NMT 0.1%                                       |
| 9.    | Loss on drying                                          | 0.26%                                       | NMT 0.5% w/w                                   |
| 10.   | Assay (ODB)<br>Potentiometer                            | 99.73%                                      | 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                                        |                                             |                                                |
| 1.    | * Bulk Density<br>1) Untapped<br>2) Tapped (50 strokes) | 0.26 gm/mL<br>0.36 gm/mL                    | Informative                                    |
| 2.    | Particle Size                                           | 100% sample passes through 40 mesh          | 100% passing through 40 mesh.                  |

\*Bulk density 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 |
|-------------------|-------------------|--------------------|--------------------|
| <br>05/10/2012    | <br>05/10/2012    | <br>05/10/2012     | <br>05/10/2012     |
| Quality Control   | Quality Control   | Quality Assurance  | Quality Assurance  |