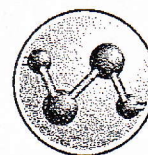
**AMRI**

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

| QUALITY CONTROL DEPARTMENT  |                                       |   |   |
|---|---------------------------------------|---|---|
| CERTIFICATE OF ANALYSIS   |                                       |   |   |
| Type: Dispatch  |                                       | Page: 1 of 2                                      |   |
| Product Name: ATENOLOL  |                                       | Batch Number: AM20112190                          |   |
| Compendia: EP   |                                       | Quantity: 250 Kg.                                 |   |
| Mfg. Date: OCT -2012  |                                       | Exp. Date: SEP-2017                               |   |
| Date of Sampling: 31/10/2012  |                                       | Date of Analysis: 31/10/2012                      |   |
| Date of Release: 05/11/2012   |                                       | A.R Number: FPA/12/241                            |   |
| 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<br>A) By Melting Point | 154°C   | First Identification C<br>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  |
| [Signature] 09/11/12  |                                       | [Signature] 09/11/2012                            | [Signature] 09/11/2012  |
| Quality Control   |                                       | Quality Control                                   | Quality Assurance   |



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**QUALITY CONTROL DEPARTMENT  
CERTIFICATE OF ANALYSIS**

|                              |                              |
|------------------------------|------------------------------|
| Type: Dispatch               | Page: 2 of 2                 |
| Product Name: ATENOLOL       | Batch Number: AM20112190     |
| Compendia: EP                | Quantity: 250 Kg.            |
| Mfg. Date: OCT -2012         | Exp. Date: SEP-2017          |
| Date of Sampling: 31/10/2012 | Date of Analysis: 31/10/2012 |
| Date of Release: 05/11/2012  | A.R Number: FPA/12/241       |

| S.No. | Test                         | Results  | Specification                                     |
|-------|------------------------------|--|---|
| 7.    | Related Substances           |  |   |
|       | Impurity B                   | 0.11%  | NMT 0.20%   |
|       | Impurities F                 | 0.09%  | NMT 0.15%   |
|       | Impurities G                 | Less than 0.05%                                | NMT 0.15%   |
|       | Impurities I                 | 0.06%  | NMT 0.15%   |
|       | Unspecified Impurities       | Less than 0.05%                                | NMT 0.10%   |
|       | Total Impurity               | 0.34 %   | NMT 0.5%  |
| 8.    | Sulphated Ash                | 0.08%  | NMT 0.1%  |
| 9.    | Loss on drying               | 0.26%  | NMT 0.5% w/w                                      |
| 10.   | Assay (ODB)<br>Potentiometer | 99.62%   | 99.0% to 101.0% w/w                               |
| 11.   | Foreign Particle             | No black Particles observed<br>on filter paper | NMT 5 black particles observed on<br>filter paper |
| 12.   | Additional Tests             |  |   |
| 1.    | * Bulk Density               |  |   |
|       | 1) Untapped                  | 0.26 gm/mL                                     | Informative                                       |
|       | 2) Tapped (50 strokes)       | 0.35 gm/mL                                     |   |
| 2.    | Particle Size                | 100% sample passes<br>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>09/11/12      | <br>09/11/2012    | <br>09/11/2012     | <br>09/11/2012     |
| Quality Control   | Quality Control   | Quality Assurance  | Quality Assurance  |