



AMRI India Pvt. Ltd. G-1/1, 1/2, MIDC Area, Waluj, Aurangabad - 431 136, India.  
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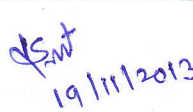
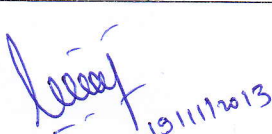
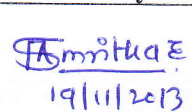
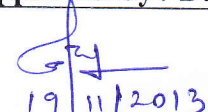
**QUALITY CONTROL DEPARTMENT**

**CERTIFICATE OF ANALYSIS**

|                              |                              |
|------------------------------|------------------------------|
| Type: Dispatch               | Page: 1 of 2                 |
| Product Name: ATENOLOL       | Batch Number: AM20113103     |
| Compendia: EP                | Quantity: 250 Kg.            |
| Mfg. Date: SEP -2013         | Retest Date: AUG-2018        |
| Date of Sampling: 11/10/2013 | Date of Analysis: 11/10/2013 |
| Date of Release: 15/10/2013  | A.R Number: FPA/13/114       |

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

| S.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  |
|       | A) By Melting Point    | 154°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>19/11/2013 | <br>19/11/2013 | <br>19/11/2013 | <br>19/11/2013 |
| Quality Control   | Quality Control   | Quality Assurance  | Quality Assurance   |





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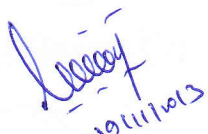
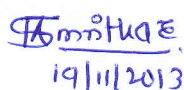
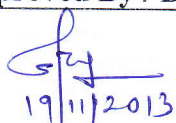
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|-------------------------------------|-------------------------------------|
| <b>Type:</b> Dispatch               | <b>Page:</b> 2 of 2                 |
| <b>Product Name:</b> ATENOLOL       | <b>Batch Number:</b> AM20113103     |
| <b>Compendia:</b> EP                | <b>Quantity:</b> 250 Kg.            |
| <b>Mfg. Date:</b> SEP -2013         | <b>Retest Date:</b> AUG-2018        |
| <b>Date of Sampling:</b> 11/10/2013 | <b>Date of Analysis:</b> 11/10/2013 |
| <b>Date of Release:</b> 15/10/2013  | <b>A.R Number:</b> FPA/13/114       |

| S.No. | Test   | Results  | Specification   |
|-------|--|--|---|
| 7.    | Related Substances<br>Impurity B<br>Impurities F<br>Impurities G<br>Impurities I<br>Unspecified Impurities<br>Total Impurity | 0.10%<br>BDRL<br>0.05%<br>0.06%<br>0.08%<br>0.33 % | NMT 0.20%<br>NMT 0.15%<br>NMT 0.15%<br>NMT 0.15%<br>NMT 0.10%<br>NMT 0.5% |
| 8.    | Sulphated Ash  | 0.08%  | NMT 0.1%  |
| 9.    | Loss on drying   | 0.32%  | NMT 0.5% w/w  |
| 10.   | Assay (ODB) by Potentiometer   | 99.62%   | 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<br>1) Untapped<br>2) Tapped (50 strokes)  | 0.24 gm/mL<br>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.

- **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>19/11/2013 | <br>19/11/2013 | <br>19/11/2013 | <br>19/11/2013 |
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