



# MEDINEX LABORATORIES PVT. LTD.

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Ref. No. \_\_\_\_\_

Drug license # G/28/83

Date: \_\_\_\_\_

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

| CERTIFICATE OF ANALYSIS                 |                                                                                                                                                                        |           |                 |                                                                                                                                                                                                         |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NAME OF THE PRODUCT                     | B.NO.                                                                                                                                                                  | MFG.DATE  | EXP. DATE       | A.R. NO.                                                                                                                                                                                                |
| Adrenaline Tartrate EP                  | MLPI/ABT/<br>0216/125                                                                                                                                                  | FEB.-2016 | JAN.-2019       | FP05/II/15-16                                                                                                                                                                                           |
| MFG. NAME                               | SAMPLED QTY                                                                                                                                                            |           | DATE OF RECEIPT | DATE OF COMPLETION                                                                                                                                                                                      |
| MEDINEX LABORATORIES<br>PVT. LTD.       | 10.0 g                                                                                                                                                                 |           | 08-02-2016      | 13-02-2016                                                                                                                                                                                              |
| TEST                                    | OBSERVATION                                                                                                                                                            |           |                 | STANDARD                                                                                                                                                                                                |
| Appearance                              | White, crystalline, powder.                                                                                                                                            |           |                 | A white or grayish-white, crystalline, powder.                                                                                                                                                          |
| Solubility                              | Freely soluble in water, slightly soluble in ethanol (96 %).                                                                                                           |           |                 | Freely soluble in water, Slightly soluble in ethanol (96%).                                                                                                                                             |
| Identification                          |                                                                                                                                                                        |           |                 |                                                                                                                                                                                                         |
| (A) SOR Test                            | (A) SOR: -50.10°                                                                                                                                                       |           |                 | (A) -50° to -53.5° (adrenaline base)                                                                                                                                                                    |
| (B) By IR Test                          | (B) Complies by IR                                                                                                                                                     |           |                 | (B) The IR spectra should concord with the reference spectra of Adrenaline tartrate WS.                                                                                                                 |
| (C) Tartrate Test                       | (C) Complies                                                                                                                                                           |           |                 | (C) A dark-blue colour develops.                                                                                                                                                                        |
| Appearance of solution                  | Complies                                                                                                                                                               |           |                 | The solution is not more opalescent than reference suspension II and is not more intensely coloured than reference solution BY.                                                                         |
| Related Substances<br>[By HPLC]         | Impurity-A: Nil<br>Impurity-B: 0.01 %<br>Impurity-C: Nil<br>Impurity-D: Nil<br>Impurity-E: Nil<br>Total Unspecified Impurities : 0.07 %<br><br>Total Impurity : 0.08 % |           |                 | Impurity-A : NMT 0.3 %<br>Impurity-B : NMT 0.2 %<br>Impurity-C : NMT 0.2 %<br>Impurity-D : NMT 0.1 %<br>Impurity-E : NMT 0.1 %<br>Unspecified impurity : Each, NMT 0.10 %<br>Total Impurity : NMT 0.6 % |
| Loss on Drying                          | 0.09 %                                                                                                                                                                 |           |                 | Maximum 0.5 %                                                                                                                                                                                           |
| Sulphated Ash                           | 0.07 %                                                                                                                                                                 |           |                 | Maximum 0.1 %                                                                                                                                                                                           |
| Assay                                   | 99.89 %                                                                                                                                                                |           |                 | 98.5 % to 101.0 %<br>(on dried basis)                                                                                                                                                                   |
| Residual Solvents [By GC]<br>[Methanol] | 0.08 %                                                                                                                                                                 |           |                 | NMT 0.3 %                                                                                                                                                                                               |
| Microbial Limit Test                    |                                                                                                                                                                        |           |                 |                                                                                                                                                                                                         |
| Total aerobic bacterial count           | <10 Cfu / g.                                                                                                                                                           |           |                 | ≤ 100 Cfu/ g.                                                                                                                                                                                           |
| Total Yeast & mold count                | <10 Cfu / g.                                                                                                                                                           |           |                 | ≤ 100 Cfu/ g.                                                                                                                                                                                           |
| Pathogen Test                           |                                                                                                                                                                        |           |                 |                                                                                                                                                                                                         |
| <i>Escherichia coli</i>                 | Absent                                                                                                                                                                 |           |                 | Absent                                                                                                                                                                                                  |
| <i>Staphylococcus aureus</i>            | Absent                                                                                                                                                                 |           |                 | Absent                                                                                                                                                                                                  |
| <i>Salmonella Spp.</i>                  | Absent                                                                                                                                                                 |           |                 | Absent                                                                                                                                                                                                  |
| <i>Pseudomonas aeruginosa</i>           | Absent                                                                                                                                                                 |           |                 | Absent                                                                                                                                                                                                  |

Opinion: The sample submitted conform with the requirement of EP - 8.0

|             |                                                           |                  |
|-------------|-----------------------------------------------------------|------------------|
| Signature   |                                                           |                  |
| Name        | Maharshi Pandya                                           | Sanjay Trivedi   |
| Designation | 1 Prabhat Nagar, 2nd Floor, Jogeshwari, Mumbai - 400 102. | Approved Chemist |

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