

## CERTIFICATE OF ANALYSIS

|  |   |                              |                                     |
|--|---|------------------------------|-------------------------------------|
| <b>Product</b>   | Esomeprazole magnesium trihydrate   |                              |                                     |
|  | CAS: 217087-09-7  |                              |                                     |
| <b>Batch No.</b>   | 20140720  | <b>Mfg. Date</b>             | Jul. 20, 2014                       |
| <b>Test Date</b>   | Jul. 22, 2014   | <b>Exp. Date</b>             | Jul. 19, 2016                       |
| <b>Items</b>   | <b>Specifications</b>   |                              | <b>Results</b>                      |
| <b>Appearance</b>  | white or slightly coloured powder, slightly hygroscopic   |                              | white powder, slightly hygroscopic  |
| <b>Identification</b>                                    | A. Infraed absorption spectrophotometry<br>Comparison: Esomeprazole magnesium trihydrate CRS                          |                              | Conforms                            |
|  | B. Atomic absorption spectrometry as described in test for magnesium  |                              | Conforms                            |
| <b>Color of solution</b>                                 | The absorbance is no greater than 0.2   |                              | 0.05                                |
| <b>Chromatographic purity</b>                            | Omeprazole N-oxide ≤ 0.1%<br>Omeprazole Sulfone ≤ 0.2%<br>Each unspecified Impurity ≤ 0.1%<br>Total Impurities ≤ 0.5% |                              | 0.02%<br>0.08%<br>Conforms<br>0.12% |
| <b>Enantiomeric purity</b>                               | R-enantiomer ≤ 0.2%   |                              | 0.08%                               |
| <b>Magnesium</b>   | 3.30% ~ 3.55% (anhydrous substance)   |                              | 3.46%                               |
| <b>Water</b>   | 6.0% ~ 8.0%   |                              | 6.82%                               |
| <b>Residual solvents</b>                                 | Acetone: ≤ 0.5%   |                              | 0.005%                              |
|  | Methanol: ≤ 0.3%  |                              | 0.011%                              |
|  | Ethyl acetate: ≤ 0.5%   |                              | 0.012%                              |
| <b>Assay</b>   | 98.0~102.0% (anhydrous substance)   |                              | 99.5%                               |
| <b>Conclusion:</b> This product conforms with the USP35. |   |                              |                                     |
| <b>Chief of QC: Li de</b>                                |   | <b>Checker: Zhang Dechen</b> | <b>Analyst: Xu lulu</b>             |