

Certificate of Analysis

| Product Name | | Esomeprazole magnesium trihydrate | Packing | 10kg per drum |
|--|-------------------------------|---|--------------|--|
| Batch No. | | D10043-20220101 | Quantity | 210kg |
| Mfg. Date | | Jan.11, 2022 | Report Date | Feb.08, 2022 |
| Retest Date | | Jan.10, 2024 | According to | EP10.0 and in house |
| ITEM | | SPECIFICATION | | TEST RESULT |
| Appearance | | White or slightly coloured powder, slightly hygroscopic. | | Slightly coloured powder, slightly hygroscopic |
| Solubility | | Slightly soluble in water, soluble in methanol, practically insoluble in heptane. | | Complies |
| Identification | 1 | The spectra obtained should be in accordance with that of esomeprazole magnesium trihydrate CRS (IR). | | Complies |
| | 2 | It should give the reaction of magnesium. | | Complies |
| Absorbance | | Not more than 0.20 (440 nm) | | 0.053 |
| Magnesium content (on the anhydrous basis) | | 3.30%~3.55% | | 3.35% |
| Water determination | | 6.2%~8.0% | | 7.05% |
| R-omeprazole | | Not more than 0.2% | | Not be detected |
| Related substances | Omeprazole sulfone | Not more than 0.15% | | 0.021% |
| | Any other individual impurity | Not more than 0.10% | | 0.043% |
| | Total impurities | Not more than 0.3% | | 0.08% |
| Residual solvents | Methylene chloride | Not more than 600 ppm | | Not be detected |
| | Methylbenzene | Not more than 890 ppm | | 52.18ppm |
| | Methanol | Not more than 3000 ppm | | 26.82ppm |
| | Ethyl acetate | Not more than 5000 ppm | | Not be detected |
| Heavy metals | | Not more than 20 ppm | | Complies |
| Assay (on the anhydrous basis) | | 98.0 % - 102.0 % | | 99.8% |
| Conclusion | | Comply with EP10.0 and in house | | |

QC Director:

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Rechecker:

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Checker:

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2022.02.08

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