武汉福鑫化工有限公司

**Wuhan Fortuna Chemical Co.,Ltd**

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# CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Product | Omeprazole | Test Basis | USP43 |
| Batch No | A-50412110004 | Mfg.Date | OCT,03.2021 |
| Exp.Date | SEP,2023 | Quantity | 320 kgs |
| ITEMS | STANDARD | | RESULTS |
| Appearance | White or almost white powder | | Complies |
| Identification | A.Thin-layer chromatography: Rf value of the principal spot observed in the chromatogram of test solution corresponds to that of the principal spot observed in the chromatogram of standard solution. | | Complies |
| | B.IR spectrophotometry: IR spectrum of omeprazole sample corresponds to that of omeprazole RS. | | Complies |
| Completeness of solution | Clear | | Complies |
| Color of solution | The absorbance at 440 nm is not greater than 0.10 | | 0.03 |
| Loss on drying | ≤0.5% | | 0.20% |
| Residue on ignition | ≤0.1% | | 0.07% |
| Heavy metals | ≤0.002% | | ＜0.002% |
| Residual solvents | Methylene chloride ≤100ppm | | 76ppm |
| | Methanol ≤1000ppm | | 22ppm |
| | Acetone ≤1500ppm | | 786ppm |
| | Toluene ≤300ppm | | 40ppm |
| | Benzene ≤1ppm | | Not detected |
| Chromatographic purity(HPLC) | 5-Methoxy-1H-benzimidazol-2-thiol ≤0.15% | | 0.03% |
| | Omeprazole N-Oxide ≤0.15% | | 0.04% |
| | Omeprazole sulfone N-Oxide ≤0.15% | | Not detected |
| | Desmethoxy omeprazole ≤0.15% | | Not detected |
| | Omeprazole sulfone ≤0.15% | | 0.02% |
| | Omeprazole 4-chloroanalog ≤0.15% | | Not detected |
| | Ufiprazole ≤0.15% | | 0.03% |
| | Any individual impurity ≤0.10% | | 0.02% |
| | Total impurities ≤1.0% | | 0.20% |
| Assay (dried substance) | 98.0%～102.0% | | 99.80%.9% |
| Conclusion | The above product conforms to USP39. | | |

QC:Luo Xiaofeng Tester: AT02 Re-tester: AT01