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Omeprazole 8.5% pellets

Product

Hefei TNJ Chemical Industry Co.,Ltd.

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| TTOUUCI | | | |
|---|------------------|--|-------------------|
| CAS No. | 73590-58-6 | Batch Number TNJ2015090606 | |
| M.F. | C17H19N3O3S | Packing 25.00kg/drum | |
| M.W. | 345.42 | MFG Date June.06, 2015 | |
| N.W. | 2,000.00kg | Analysis Date June.06, 2015 | |
| G.W. | 2,120.00kg | Retest Date June.05, 2017 | |
| 0 | ý C | | |
| | Items | Specification | Results |
| | Appearance | White to off white colored spherical pellets | Confirms |
| Identificat | tion by HPLC | The retention time of principle peak obtained with the sample preparation corresponds to that of standard preparation as obtained in | |
| Moisture content | | assay | 1.25% |
| | Bulk density | Not more than 2.0%W/W | 0.80gm/ml |
| 0.70gm/ml to 0.90 gm/ml | | o " | |
| Uniformity of dosage units Confirm | | Confirms | |
| | Pellet size | | Confirms |
| Gas | stric-resistance | Not less than 95.0% should pass through 12mesh Not less than 5.0% should pass through 16mesh | Confirms 3.13% |
| | | Not more than 15% of labeled amount of omeprazole shall dissolve in | 89.21% |
| Dissolution in buffer N | | 0.1N HCL Not more than 75% of labeled amount of omeprazole should dissolve in | 09.21% |
| Related substances (by HPLC) | | PH6.8 phosphate buffer after 30 minute Thioxopyrido conversion:not more than 0.5% | 0.05% 0.12% |
| | | 5-methoxy-1 H-benzimidazole-2-thiol:not more than 0.5% | 0.05% |
| | A = = = | any other individual impurity:not more than 0.5% | 0.55% 100.2% |
| Assay | | Total impurity :not more than 2.0% Not more than 90.0% and not more than 110.0% of labelled amount of | 100.276 |
| Residual solvents | | omeprazole USP | |
| | Aceton | Not more than5000ppm | 610ppm |
| Methanol | | Not more than3000ppm | 402ppm |
| Methylene dichloride Not more than600ppm | | Not more than600ppm | 110ppm |
| | Toluene | Not more than890ppm | 69ppm |
| | Checker Xu Don | g Re-checker Lu Xiaoping Approval Liu Wu | |
| Conclusion The Quality of the above said is in conformity with USP. | | | |
| COA Issuer Quality Control Tea of Hefei TNJ Chemi | | Team-Technology Department | |
| | | IN THE LINE | |
| | | nical Industry Co., Ltd. | |
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