

## CERTIFICATE OF ANALYSIS

### Rabeprazole sodium

<b>Batch No.:</b> DR20160901	<b>Piece:</b> 150kg
<b>Manufacture Date:</b> 2016.09.01	<b>Expiry Date:</b> 2021.08

**TESTS:**

Items	Specification	Results
Characteristics	A white to light yellow crystalline powder, hygroscopic	Light yellow crystalline powder
Solubility	Soluble in water	Conforms
Identification by	1) IR: The infrared absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wavenumbers as that of the similar preparation of rabeprazole sodium working standard. 2) Sodium: 10% w/v solution in carbon dioxide-free water gives reaction of sodium.	Conforms
Water content by KF	≤7.00% w/w	3.6%
Heavy metals	≤20ppm	< 20ppm
Related substance by hplc	Impurity A(Sulphone): ≤0.5% Impurity B(Sulphide): ≤0.5% Maximum single unknown impurity: ≤0.5% Total impurities: ≤1.5%	0.05% N.D. 0.28% 0.93%
Assay by HPLC(on anhydrous basis)	98.0%~102.0%	99.6%
Residual solvents by GC	Methanol: ≤3000ppm Acetone: ≤5000ppm Methylene chloride: ≤600ppm Cyclohexane: ≤3880ppm	195ppm 118ppm N.D. N.D.

Conclusion: The results conform with USP and Enterprise standard.



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