

Graviti Pharmaceuticals Private Limited
Abbreviated New Drug Application
Pantoprazole Sodium Delayed-Release Tablets, USP 20 mg and 40 mg

3.2.P.5.2 Analytical Procedures

The drug product Pantoprazole Sodium Delayed-Release Tablets, USP 20 mg and 40 mg is official in USP.

The reference for analytical test procedure used for the analysis of Pantoprazole Sodium Delayed-Release Tablets, USP 20 mg and 40 mg are given in table below.

S. No.	Test	Reference or Analytical Procedure Code
1	Description	In-House
2	Identification	
	A. HPLC	USP
	B. By UV	In-House
3	Assay (By HPLC)	In-House
4	Dissolution (By HPLC)	In-House
5	Uniformity of Dosage Units (By HPLC)	In-House
6	Organic Impurities (By HPLC)	In-House
7	Water Content (By KF)	In -House
8	Average Weight	USP
9	Residual Solvents	USP <467>
10	Elemental Impurities	USP <232>

The standard analytical test procedure ([STP-FP-0051-01](#)) for release and ([STP-SL-0051-01](#)) for shelf-life used for testing the drug product in routine and on stability are provided in this section.