## 3.2.S.4.2 Analytical Procedures

The drug substance used in the manufacture of drug product (Pantoprazole Sodium Delayed-Release Tablets, USP 20 mg and 40 mg) has been procured from Vasudha Pharma Chem Limited.

The reference for analytical test procedures used for the analysis of drug substance are tabulated below:

| S. No. | Test | Reference or Analytical Procedure Code |
|---|---|---|
| 1 | Description | Visual |
| 2 | Solubility | USP |
| 3 | Identification | |
| | A. By Infrared Spectroscopy | USP<197K> |
| | B. By HPLC | USP |
| | C. Test for Sodium | USP<191> |
| 4 | Assay (By HPLC) | USP |
| 5 | Organic impurities (By HPLC) | USP |
| 6 | Water Content (By KF) | In-House Method |
| 7 | Residual Solvents (By HS-GC) (Method A & Method B) | |
| | A. Method A | In-House Method |
| | B. Method B | In-house Method |
| 8 | Particle Size Distribution (By Malvern Mastersizer) | In-House Method |

The drug product manufacturer's Standard Test Procedure (STP-DS-0037-02) used for testing of drug substance is provided in this section.