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

3.2.P.4.2 Analytical Procedures

Crospovidone USP-NF (Crospovidone XL-10) is official in current USP-NF monograph. The current USP-NF monograph methodologies have been followed during analysis for Crospovidone USP-NF (Crospovidone XL-10), except for In-House test i.e., pH, water content and Microbial Enumeration tests and tests for specified microorganisms.

For In-house test i.e., pH, water content and Microbial Enumeration tests and tests for specified microorganisms vendor's method has been followed.