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

Ferric oxide USP-NF (Iron oxide Sicovit Yellow 10E 172 is official in current USP-NF monograph. The current USP-NF monograph methodologies have been followed during analysis for Ferric oxide USP-NF (Iron oxide Sicovit Yellow 10E 172, except for In-house test i.e., Loss on Ignition, pH, Loss on Drying, Sieve Residue on 44μ and Microbial Enumeration Tests and Tests for specified microorganisms.

For Loss on Ignition, pH, Loss on Drying, Sieve Residue on 44µ and Microbial Enumeration Tests and Tests for specified microorganisms, vendor's methodologies have been adopted.