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3.2.P.5 Control of the drug product**3.2.P.5.3 Validation of Analytical Procedures**

The finished product Silodosin 8 mg capsules, hard is analysed as per Pharmacopoeial and In-House specification.

Please find below mentioned analytical method validation of Assay, Content Uniformity, Dissolution, Related substance and Microbial Limit test is enclosed in following page:

Sr. No.	Analytical Method Validation
1	Analytical Method validation for the test of Assay, Identification, Uniformity of dosage unit by content uniformity, Blend Assay and Blend uniformity of Silodosin Capsules 8 mg.
2	Analytical Method validation for the test of Dissolution for Silodosin Capsules 8 mg.
3	Analytical Method validation for the test of Related Substance for Silodosin Capsules 8 mg.
4	Analytical Method validation for Forced degradation for Silodosin Capsules 8 mg.
5	Analytical Method validation for water content for Silodosin Capsules 8 mg.
6	Analytical Method validation for the test of Microbial Limit Test for Silodosin Capsules 8 mg.
7	Analytical Method validation for the determination of N-Nitroso Silodosin content in Silodosin Capsules 8 mg.

AMV Protocol & Report

**(Assay, Identification, Uniformity of dosage unit by content
uniformity, Blend Assay and Blend uniformity)**

AMV Protocol & Report
(Dissolution)

AMV Protocol & Report
(Related Substance)

AMV Protocol & Report
(Forced Degradation)

AMV Protocol & Report
(Water Content)

AMV Protocol & Report (Microbial Limit Test)