

QUALITY CONTROL DEPARTMENT
[Certificate of Analysis Finished product]
 (FORM 39, RULE 150 E (F) THE DRUG AND
 COSMETIC ACT, 1940 AND THE RULES THERE UNDER)

Product Name	: Nitrosmart 2.6	AR Number	: FP-07-2024/0465
Generic Name	: Nitroglycerin Controlled Release Tablets 2.6 mg	Sample Quantity	: 100 Tab
Batch No.	: KTB267B	Manufactured By	: Kureasia pharma Pvt.Ltd.
Batch Size	: 3.0 Lac	Manufactured For	: Healing Pharma India Pvt Ltd.
Date of Received	: 10/07/2024	Manufacturing Date	: 07/2024
Date of Analysis	: 10/07/2024	Expiry Date	: 06/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 13/07/2024
Reference Protocol No.	: KP/QC/FPS/021		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	Description	Pink coloured, round, biconvex, uncoated controlled release tablets.	Pink coloured, round, biconvex, uncoated controlled release tablets.
2.	Identification <i>By High Performance Liquid Chromatography</i>	Meet the Requirement	In the assay, The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Dissolution Test <i>(By High Performance Liquid Chromatography)</i> 1st Hour 3rd Hour 10th Hour	 21.50% to 24.69% 48.68% to 51.62% 89.42% to 91.82%	 Not More than 30.0% of the labeled amount. Between 30.0% to 60.0% of the labeled amount. Not less than 75% of the stated amount.
4.	Uniformity of content <i>(By High Performance Liquid Chromatography)</i>	86.07% to 104.54%	85.00 % to 115.00 % of the labeled amount.
5.	Assay : <i>(By High Performance Liquid Chromatography)</i> Each Uncoated Controlled Release tablet contains: Diluted Nitroglycerin IP Equivalent to Nitroglycerin 2.6 mg (in a controlled release from)	2.65mg	Shelf Life Limit: Not less than 2.34 mg and not more than 2.86 mg. (Not less than 90.00 % and not more than 110.00 % of Label Claim) Release Limit: (Not less than 95.00% and not more than 105.00% of Label Claim) Not less than 2.47 mg and not more than 2.73 mg

ADDITIONAL TEST

6.	Average Weight	181.16 mg	180.00 mg $\pm$ 7.5 %
7.	Uniformity of Weight	-1.36% to +1.29 %	Not more than 2 of the individual weight deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15.0% of the average weight.
8.	Friability Test	0.20%	Not more than 1.0%

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Remark: Product complies /does not complies as per IP/BP/USP/IH specification.

Analyzed By :	Reviewed By :	Approved by
Sign/ Date <i>KCO</i> 13/07/2024	Sign/Date <i>A</i> 13/07/2024	Sign/Date <i>G</i> 13/07/2024