

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	DAPASMART TRIO FORTE 1000 TABLETS		
Generic Name/Dosage Form Strength (mg)	Dapagliflozin 10 mg, Sitagliptin 100 mg and Metformin Hydrochloride (ER) 1000 mg Tablets		
Batch No.	WDRT324001	A.R. No.	QC/FG/24/00686
Batch Size	50000 TABLET	Pack Size	1 X 10 TABS
Mfg. Date	01/2024	Exp. Date	12/2025
Reference	IH	Market	Domestic
Sample Received on	21/01/2024	Sample Qty.	1x100 TABLET
Ref. STP No.	WBL/STP/FG/0982 (current version)	Ref. SPS No.	WBL/FPS/FG/P3/1037
Date of Analysis started on	28/01/2024	Date of Analysis completed on	13/02/2024
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S.No.	Test	Specification	Result
1	Description	White to off white & Light Pink coloured, elongated, biconvex, bilayered, film coated tablet, plain on both sides.	White & Light Pink coloured, elongated, biconvex, bilayered, film coated tablet, plain on both sides.
2	Identification	In the assay, the peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the standard solution.	Complies
3	Length	20.00 mm to 20.40 mm	Min : 20.28 mm Max : 20.31 mm
4	Width	9.30 mm to 9.70 mm	Min : 9.55 mm Max : 9.59 mm
5	Thickness	8.40 mm to 8.80 mm	Min : 8.42 mm Max : 8.57 mm
6	Average weight	1542.30 to 1637.70 mg	1589.194 mg
7	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5%. No tablet deviates from the average weight by more than 10%.	Deviation : - 2.136 % to + 2.312 %
8	Dissolution		
8a.	1st hour Metformin Hydrochloride IP	25.0 to 50.0% of labeled amount	Min : 29.5 % Max : 31.7 % Avg : 30.5 %

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	DEEPENDRA SINGH	Shubham Juyal	ANKITA GAUR	Jogendra Singh
Designation	TRAINEE CHEMIST	Officer	Sr. Officer	G. M.
Date	13/02/2024	13/02/2024	14/02/2024	14/02/2024

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S.No.	Test	Specification	Result
8b.	3rd hour Metformin Hydrochloride IP	45.0 to 85.0% of labeled amount	Min : 55.1 % Max : 59.0 % Avg : 57.2 %
8c.	10th hour Metformin Hydrochloride IP	Not less than 75.0% of labeled amount	Min : 95.1 % Max : 98.5 % Avg : 97.1 %
8d.	Dissolution Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin	Not less than 75.0% of labeled amount	Min : 87.0 % Max : 97.1 % Avg : 91.1 %
8e.	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin	Not less than 75.0% of labeled amount	Min : 81.9 % Max : 93.7 % Avg : 86.8 %
9	Uniformity of Dosage Units		
9a.	(By Content Uniformity) Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin	Acceptance value should be less than 15	8.80
9b.	(By Content Uniformity) Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin	Acceptance value should be less than 15	9.98
9c.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	4.20
10	Residual Solvents		

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S.No.	Test	Specification	Result
10a.	Isopropyl Alcohol	Not more than 5000 ppm	422 ppm
10b.	Dichloromethane	Not more than 600 ppm	12 ppm
11	Assay Each film coated bilayered tablet contains:		
11a.	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin...10mg	90.0 to 110.0% of labeled amount	98.3 %
11b.	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin...100mg	90.0 to 110.0% of labeled amount	99.6 %
11c.	Metformin Hydrochloride IP (as extended release form)...1000mg	90.0 to 110.0% of labeled amount	98.2 %

Remarks : In the opinion of undersigned the sample refer to above specifications complies with IH

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