

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	PANTODICE DSR CAPSULES		
Generic Name/Dosage Form Strength (mg)	Pantoprazole Gastro-Resistant 40 mg & Domperidone Prolonged-Release 30 mg Capsules IP		
Batch No.	PDT24006	A.R. No.	QC/FG/24/04324
Batch Size	100000 STRIP	Pack Size	01 X 10 CAPSULE
Mfg. Date	04/2024	Exp. Date	03/2026
Reference	I.P	Market	Domestic
Sample Received on	07/05/2024	Sample Qty.	1x75 CAPSULE
Ref. STP No.	WBL/STP/FG/0042	Ref. SPS No.	WBL/FPS/FG/5776
Date of Analysis started on	08/05/2024	Date of Analysis completed on	27/05/2024
Page No.	01 of 03		

S.No.	Test	Specification	Result
1	Description	Pink Transparent Cap / Clear Transparent Body, size '2' hard gelatin capsules containing Blue & Orange coloured spherical pellets.	Pink Transparent Cap / Clear Transparent Body, size "2" hard gelatin capsules containing Blue & Orange coloured spherical pellets.
2	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution correspond to the chromatogram obtained with the reference solution.	Complies
3	Average weight of filled capsule	324.95 to 345.05 mg	333.99 mg
4	Average fill weight of capsule	261.90 to 278.10 mg	271.77 mg
5	Uniformity of fill weight of capsule	Not more than 2 capsules in 20 deviates from the average fill weight by more than 7.5%. No capsule deviates from the average fill weight by more than 15.0%.	-2.66% to +3.21%
6	Dissolution		
6a.	1st hour Domperidone IP	15.0 to 40.0%	Min-28.2% Max-32.9% Avg-30.2%
6b.	4th hour Domperidone IP	30.0 to 60.0%	Min-53.1% Max-59.7% Avg-55.3%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Deepu	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager-QA	G. M.
Date	27/05/2024	28/05/2024	28/05/2024	29/05/2024

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Page No.	02 of 03		

S.No.	Test	Specification	Result
6c.	12th hour Domperidone IP	Not less than 70.0%	Min-85.5% Max-96.3% Avg-89.3%
6d.	In 0.1M Hydrochloric Acid Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 10.0% of labeled amount in 2 hrs.	Min-5.0% Max-7.6% Avg-6.2%
6e.	In phosphate buffer pH 6.8 Pantoprazole Sodium IP eq. to Pantoprazole	Not less than 70% (Q) of the stated amount in 45 minutes	Min-85.4% Max-89.4% Avg-87.1%
7	Related substances		
7a.	Related Compound A Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.5%	Not Detected
7b.	Related Compound B Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.3%	Not Detected
7c.	Related Compound D and F Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.75%	0.005%
7d.	Any other secondary peak Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.2%	0.152%
7e.	Sum of All Secondary Peak Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 1.5%	0.233%

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Page No.	03 of 03		

S.No.	Test	Specification	Result
7f.	Any other secondary peak Domperidone IP	Not more than 0.5%	0.067%
7g.	Sum of All Secondary Peak Domperidone IP	Not more than 2.0%	0.067%
8	Assay Each hard gelatin capsule contains:		
8a.	Domperidone IP (as orange colour prolonged-release pellets)...30mg	90.0 to 110.0%	99.8%
8b.	Pantoprazole Sodium IP eq. to Pantoprazole (as blue colour gastro-resistant pellets)...40mg	90.0 to 110.0%	102.7%

Remarks : In the opinion of undersigned the sample refer to above specifications complies with I.P

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Deepu	Lakshay	Jogendra Singh
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