

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.	PDT24008	A.R. No.	QC/FG/24/07595
Batch Size	50000 STRIP	Pack Size	01 X 10 CAPSULE
Mfg. Date	07/2024	Exp. Date	06/2026
Reference	I.P	Market	Domestic
Sample Received on	29/07/2024	Sample Qty.	1x75 CAPSULE
Ref. STP No.	WBL/STP/FG/0042	Ref. SPS No.	WBL/FPS/FG/5776
Date of Analysis started on	30/07/2024	Date of Analysis completed on	23/08/2024
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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	335.28mg
4	Average fill weight of capsule	261.90 to 278.10 mg	272.85 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%.	-3.42% to +2.70%
6	Dissolution		
6a.	1st hour Domperidone IP	15.0 to 40.0%	Min-34.5% Max-36.9% Avg-35.6%
6b.	4th hour Domperidone IP	30.0 to 60.0%	Min-48.8% Max-53.7% Avg-51.2%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Atul Kumar	Deepu	Lakshay	Deepak Kumar
Designation	Executive	Assistant Manager	Assistant Manager-QA	Manager
Date	23/08/2024	24/08/2024	25/08/2024	25/08/2024

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S.No.	Test	Specification	Result
6c.	12th hour Domperidone IP	Not less than 70.0%	Min-80.3% Max-89.5% Avg-84.9%
6d.	In 0.1M Hydrochloric Acid Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 10.0% of labeled amount in 2 hrs.	Min-0.0% Max-1.4% Avg-0.4%
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-85.5% Max-88.3% Avg-86.7%
7	Related substances		
7a.	Related Compound A Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.5%	0.327%
7b.	Related Compound B Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.3%	0.003%
7c.	Related Compound D and F Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.75%	0.044%
7d.	Any other secondary peak Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 0.2%	0.110%
7e.	Sum of All Secondary Peak Pantoprazole Sodium IP eq. to Pantoprazole	Not more than 1.5%	0.626%

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S.No.	Test	Specification	Result
7f.	Any other secondary peak Domperidone IP	Not more than 0.5%	Below Disregard Limit
7g.	Sum of All Secondary Peak Domperidone IP	Not more than 2.0%	Below Disregard Limit
8	Assay Each hard gelatin capsule contains:		
8a.	Domperidone IP (as orange colour prolonged-release pellets)...30mg	90.0 to 110.0%	104.2%
8b.	Pantoprazole Sodium IP eq. to Pantoprazole (as blue colour gastro-resistant pellets)...40mg	90.0 to 110.0%	100.7%

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	Atul Kumar	Deepu	Lakshay	Deepak Kumar
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