

AR. No. : F000002416	FINISH PRODUCT CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT	

Product Name :	PROZCAN-DSR CAPSULES		
Generic Name :	Pantoprazole Gastro-Resistant and Domperidone Prolonged-Release Capsules IP		
Batch No. :	MCD0105A	Batch Size :	175000 CAPSULES
Mfg. Dt :	Oct. 2024	Report No. :	F000002416
Exp.Dt :	Sep. 2026	Report Date :	21/11/2024

TEST	RESULTS	LIMITS
Description	Orange and Blue coloured spherical pellets filled in pink transparent cap and clear transparent body hard gelatin capsules of size "1".	Orange and Blue coloured spherical pellets filled in pink transparent cap and clear transparent body hard gelatin capsules of size "1".
Identification	Complies	In the assay, principal peak in the chromatogram obtained with the test solution correspond to chromatogram obtained with standard solution. (By HPLC)
Average weight	351.32 mg	320.05 to 371.95mg
Uniformity of weight	Deviation: -3.88% to +3.83%	Not more than 2 capsules out of 20 capsules should deviate from the average weight by 10 % and none should deviate by more than 20.0%.
Dissolution Pantoprazole	A (By HPLC) a) Acid stage: MIN: 2.4%, MAX: 11.2%, AVERAGE: 6.8% b) Buffer stage: MIN: 80%, MAX: 90%, AVERAGE: 83%	(By HPLC) a) Acid stage: NMT 15.0 % of label claim should dissolve in 0.1N HCL after 2 hrs. b) Buffer stage: NLT 70.0 % (Q) average value of the label claim, remain dissolved in phosphate buffer pH 6.8 within 45 minutes.
Domperidone	B (By HPLC) a) 1 st hour : MIN: 21.83%, MAX: 36.77%, AVERAGE: 28.70% b) 4 th hour : MIN: 39.10%, MAX: 64.21%, AVERAGE: 50.36% c) 8 th hour : MIN: 50.41%, MAX: 84.50%, AVERAGE: 66.80% d) 12 th hour : MIN: 68.39%, MAX: 111.57%, AVERAGE: 85.57%	(By HPLC) a) 1 st hour : 10.0 % to 45.0 % b) 4 th hour : 25.0 % to 65.0 % c) 8 th hour : 50.0 % to 85.0 % d) 12 th hour : NLT 65.0 %
Water content	3.80 %	NMT 10.00%
Assay	OBTAINED CLAIM	Limits
Pantoprazole IP	A 39.320000mg 40.000000mg 98.30%	36.000000mg/cap to 44.000000mg/cap 90.00% to 110.00%
Domperidone IP	B 30.340000mg 30.000000mg 101.13%	27.000000mg/cap to 33.000000mg/cap 90.00% to 110.00%

	Prepared By	Checked By	Approved By
Name	Monali N. Patel	Rajesh B. Chavda	Yogesh Pujara
Date	21/11/2024	21/11/2024	21/11/2024
Designation	Sr. Executive Q.C.	Dy. Manager Q.C.	Manager Q.C.

AR. No. : F000002416	FINISH PRODUCT CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT	

Product Name : PROZCAN-DSR CAPSULES	
Generic Name : Pantoprazole Gastro-Resistant and Domperidone Prolonged-Release Capsules IP	
Batch No. : MCD0105A	Batch Size : 175000 CAPSULES
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TEST	RESULTS	LIMITS
Related substances Pantoprazole A	a) Impurity A : 0.099% b) Impurity B : 0.006% c) Impurity D & F : 0.028% d) Any other secondary impurity : 0.033% e) Total impurity : 0.277%	a) Impurity A : NMT 0.5 % b) Impurity B : NMT 0.3 % c) Impurity D & F : NMT 0.75 % d) Any other secondary impurity : NMT 0.5 % e) Total impurity : NMT 1.5 %
Domperidone B	a) Any other secondary impurity : 0.41% b) Total impurity : 0.49%	a) Any other secondary impurity : NMT 0.5 % b) Total impurity : NMT 2.0 %
Microbial limit test		
Total aerobic microbial count	10 cfu/gm	Not more than 1000 cfu/gm
Total combined Yeast and Moulds count	< 10 cfu/gm	Not more than 100 cfu/gm
E.Coli	Complies	Absent/gm

Remarks:The sample complies as per specification. FP/1500001891/F (Pack: 10 X 10 Caps)

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