

AR. No. : F000002908	<b>FINISH PRODUCT CERTIFICATE OF ANALYSIS</b>
<b>QUALITY CONTROL DEPARTMENT</b>	

<b>Product Name</b> :	PROZCAN-DSR CAPSULES	<b>Batch Size</b> :	225000 CAPSULES
<b>Generic Name</b> :	Pantoprazole Gastro-Resistant and Domperidone Prolonged-Release Capsules IP	<b>Report No.</b> :	F000002908
<b>Batch No.</b> :	NCD0001A	<b>Report Date</b> :	31/01/2025
<b>Mfg. Dt</b> :	Jan. 2025		
<b>Exp.Dt</b> :	Dec. 2026		

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	351.75 mg	320.05 to 371.95mg
Uniformity of weight	Deviation: -3.80% to +3.47%	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	a) Acid stage: Min: 7.9%, Max: 8.0%, Mean: 7.9% b) Buffer stage: Min: 83%, Max: 98%, Mean: 90%	(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	a) 1 <sup>st</sup> hour : Min: 27.81%, Max: 34.19%, Mean: 32.06% b) 4 <sup>th</sup> hour : Min: 46.61%, Max: 59.94%, Mean: 52.32% c) 8 <sup>th</sup> hour : Min: 52.09%, Max: 82.22%, Mean: 71.18% d) 12 <sup>th</sup> hour : Min: 70.79%, Max: 95.04%, Mean: 83.50%	(By HPLC) a) 1 <sup>st</sup> hour : 10.0 % to 45.0 % b) 4 <sup>th</sup> hour : 25.0 % to 65.0 % c) 8 <sup>th</sup> hour : 50.0 % to 85.0 % d) 12 <sup>th</sup> hour : NLT 65.0 %
Water content	4.14 %	NMT 10.00%
Assay	<b>OBTAINED</b> <b>CLAIM</b>	<b>Limits</b>
Pantoprazole IP A	39.028047mg                      40.000000mg 97.57%	36.000000mg/cap to 44.000000mg/cap 90.00% to 110.00%
Domperidone IP B	29.234860mg                      30.000000mg 97.45%	27.000000mg/cap to 33.000000mg/cap 90.00% to 110.00%

	Prepared By	Checked By	Approved By
<b>Name</b>	Sandip B. Patadiya	Rajesh B. Chavda	Dr. Manojkumar Dubey
<b>Date</b>	31/01/2025	31/01/2025	31/01/2025
<b>Designation</b>	ANALYST	Dy. Manager Q.C.	G.M. Q. C.

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TEST	RESULTS	LIMITS
Related substances Pantoprazole A	a) Impurity A : Not detected b) Impurity B : 0.003% c) Impurity D & F : Not detected d) Any other secondary impurity : 0.046% e) Total impurity : 0.119%	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 : 0.154% b) Total impurity : 0.466%	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 cap)

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<b>Name</b>	Sandip B. Patadiya	Rajesh B. Chavda	Dr. Manojkumar Dubey
<b>Date</b>	31/01/2025	31/01/2025	31/01/2025
<b>Designation</b>	ANALYST	Dy. Manager Q.C.	G.M. Q. C.