



SALUS PHARMACEUTICALS  
480/211, Vill. Harraipur, P.O. Gurumajra, Nalagarh Road  
Baddi -173205

QUALITY CONTROL  
DEPARTMENT

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Mfg. License No.: MNB/06/382/&MB/06/383

Product Name	Prozcan-DSR Capsules	A.R. No.	FP032404093
Generic Name	Pantoprazole Enteric coated and Domperidone Sustained Release Capsules IP	Batch Size	3.0 lac
Batch No:	SPC240414A	Sample Qty.	60 Capsules
Mfg. Date	03/2024	Sampled By	Shyam
Exp. Date	02/2026	Date of Sampling	09/03/2024
Mfd. By	Salus Pharmaceuticals	Date of Completion	12/03/2024

RESULT OF ANALYSIS

S.No.	TEST PARAMETER	SPECIFICATION	RESULT
01.	Description	Pink colour cap and transparent body, cylindrical shape, hard gelatin capsules filled with multi colour pellets	Pink colour cap and transparent body, cylindrical shape, hard gelatin capsules filled with multi colour pellets
02.	Identification	To be comply	Complies
03.	Average weight	360.0mg $\pm$ 7.5%w/w	360.13mg
04.	Average fill weight	300.0mg $\pm$ 7.5%w/w	297.19mg
05.	Uniformity of filled weight	300.0mg $\pm$ 7.5%w/w	+5.11% to -3.66%
06.	Disintegration	NMT 30 Minutes	9min, 11 sec.
07.	Dissolution Test (Domperidone)		
	After 1st Hour	15% To 40%	32.94%
	After 4 <sup>th</sup> Hour	30% to 60%	47.85%
	After 8 <sup>th</sup> Hour	55% to 85%	65.72%
	After 12 <sup>th</sup> Hour	Not Less than 70%	77.83%
08.	Dissolution: Pantoprazole sodium In 0.1M HCl for 2 hours Tris-acetate buffer solution pH 6.8 for 45 minutes	Not more than 10%  Q. Not less than 70.0%	3.28%  81.29%
09.	Assay: - Each hard gelatin capsule Contains.		
	Pantoprazole sodium IP Eq. To Pantoprazole 40 mg (as enteric coated pellets)	36.0mg to 44.0mg (90.0% to 110.0%)	39.34mg (98.35%)
	Domperidone IP 30 mg (as sustained release pellets)	27.0mg to 33.0mg (90.0% to 110.0%)	29.18mg (97.26%)

Remark: In the opinion of undersigned the sample referred to above is of Standard Quality/Not standard quality as defined in the Act and rules made there under for reason(s) given below complies with above test IP/BP/USP/ In-House Specification.

S. No.	Analysed By	Checked By	Approved By
Designation	Q.C. Chemist	SR.QC Executive	QC Manager
Sign. & Date	 12/03/2024	 12/03/2024	 12/03/2024