



PETROFAC LIMITED
 UNIT 1, VESZ JUNCTION
 Plot 1, 1st Floor, 77/79, 80/82, 83/85,
 1st Floor, 86/88, 89/91, 92/94,
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PHARMACEUTICALS LIMITED
 UNIT 5/132 (U111)
 Plot 1/1, Sector 132, 440, 44 & 45,
 TIC, Faridkot District,
 Punjab 151 001, India
 Telephone No. (0161) 260 111

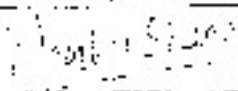
		Certificate No. Сертификат №	MSFP20116606	Сторінка 3 з 5 Page 3 of 5
5	Розміщення (Метод УВЧ) Висвітлення Гідроліз кислотності Хроматографія 1200 мд, 10 мін 1000 мд, 10 мін 1000 мд, 10 мін	При розпуску і на вмісту призначення		
	Гідроліз (метод УВЧ) Гідроліз реш pH 6.8 1000 мд	Не більше 10% від значення вмісту призначення (C ₁₂ H ₁₁ F-N-C ₁₂ S) розчиняється в 2 частини		
	Гідроліз (метод УВЧ) Гідроліз реш pH 6.8 1000 мд	Не більше 10% від значення вмісту призначення (C ₁₂ H ₁₁ F-N-C ₁₂ S) розчиняється в 2 частини		
6	Uniformity of dosage units (by HPLC) Acceptance value (U.S.) Contention допустимі значення (метод ВРМ) Maximum difference максимальна різниця (метод ВРМ) (U.S.)	Відповідно		
	Acceptance value (U.S.)	Not more than 15.0		
	Contention допустимі значення (метод ВРМ)	Not more than 15.0		
7	Related substances (by HPLC) Related compound A Related compound B Related compound C & F Maximum single unknown impurity Total impurities	Related and Similar-type		
	Related compound A	Not more than 0.5 % m/m		
	Related compound B	Not more than 0.5 % m/m		
8	Суміш домішок (метод ВРМ) Домішок А Домішок В Домішок С & F Максимальна невідома різниця (метод ВРМ) (U.S.)	Відповідно		
	Домішок А	Not more than 0.5 %		
	Домішок В	Not more than 0.5 %		
9	Суміш домішок (метод ВРМ) Домішок А Домішок В Домішок С & F Максимальна невідома різниця (метод ВРМ) (U.S.)	Відповідно		
	Домішок А	Not more than 0.5 %		
	Домішок В	Not more than 0.5 %		



			Certificate No.: Сертифікат №	SSFP25016606	Page 5 of 5 Страница 5 з 5
Sl	Identification of Release coloursant (s)				
	A. Titanium dioxide	A pale yellow colour to orange colour should develop immediately.		Complies	
	B. Iron oxide	A red colour should develop which does not disappear upon addition of dilute hydrochloric acid		Complies	
	Identification Сарвнант (s)				
	A. Titanium dioxide	Пале жовте до помаранчевого забарення розвивається негайно		Відповідає	
	B. Iron oxide	Червоний колір розвивається негайно та не зникає після додавання розведеної соляної кислоти		Відповідає	
	Labelling	Should correspond to the requirements of MOC.		Complies	
	Маркування	Повинно відповідати вимогам МОН.		Відповідає	
	Packaging	Should correspond to the requirements of MOC.		Complies	
	Пакування	Повинно відповідати вимогам МОН.		Відповідає	

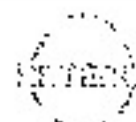
I hereby certify that the above information is authentic and accurate. The batch of product has been manufactured, including packaging/labelling and quality control as the above mentioned site to full compliance with the requirements specified in the current GMP guidelines issued by the Ministry of Health of Karnataka and with the requirements of the registration dossier of the destination country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Я тим самим гарантую, що вищевказана інформація є достовірною та точною. Ця серія продукції була вироблена відповідно до вимог реєстраційного довідника на цій території в повній відповідності з вимогами, вказаними в поточних GMP, випущених Міністерством охорони здоров'я Карнатаки, і з вимогами реєстраційного довідника країни призначення. Промислові записи виробництва, пакування та аналізу були перевірені та знайдені в повній відповідності з GMP.

Position of person authorising the batch release Підпис особи, яка погоджує партію на випуск серії	Name NEELSHU S. ARMA Manager - Quality Assurance Менеджер із забезпечення якості
Signature of person authorising the batch release Підпис особи, яка погоджує партію на випуск серії	
Date of signature Дата підписання	28.05.2026

HETERO LABS LIMITED

Unit-V, TSIC Formulation SE2, S. No. 439,440,441 & 459,
Polapally Village, Jadcherla, Mahaboob Nagar - 509301,
Telangana State, INDIA.

**CERTIFICATE OF ANALYSIS**

Product Name: PANTOPRAZOLE HETERO/PANTOPRAZOLE 30MG GASTRO RESISTANT TABLETS			
Product Code	4226022	A.R. No.	SEP2601603
Specification ID	PHARM/01/01/00	Batch No	10260729
Mfg. Date	28/06/25	Batch Size	210000 Tablets
Exp. Date	26/02/27	Date Of Release	26/06/2025 10:07
Re-test Date	-	Market	UKRAINE

S. No	TEST	RESULT	SPECIFICATION
1	Description (Visual Inspection)	Yellow over white, gastro resistant tablets imprinted with '125' on one side with 'HLS' and a star on the other side.	Yellow to pale yellow over white, gastro resistant tablets imprinted with '125' on one side with 'HLS' and a star on the other side.
2	Identification		
2.1	By UV (Ph. Eur. 2.2.25 & In-House)	The UV absorption spectrum of the sample solution exhibits maxima at the same wavelengths as that of standard solution.	The UV absorption spectrum of the sample solution should exhibit maxima at the same wavelengths as that of standard solution.
2.2	By HPLC (Ph. Eur. 2.2.29 & In-House)	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the Assay.	The retention time of the major peak in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the Assay.
3	Average weight (mass) (In-House)	102.41 mg	103.2mg ± 4% (100.57mg - 107.22mg)
4	Water content (By KF) (Ph. Eur. 2.5.12, Method A)	4.0 % w/w	5 % w/w Limit Not more than 10.0 % w/w Stability Limit Not more than 5.0 % w/w
5	Dissolution (By UV) (Ph. Eur. 2.9.3, 2.2.25 & In-House)		
5.1	Acid stage (0.1N Hydrochloric acid, 1000ml., Paddle, 100 RPM)	Tablet-1 : 0 % Tablet-2 : 0 % Tablet-3 : 0 % Tablet-4 : 0 % Tablet-5 : 0 % Tablet-6 : 2 % Average: 5 %	Not more than 10% of the labeled amount of Pantoprazole (C ₁₆ H ₁₅ F ₂ N ₃ O ₄ S) is dissolved in 2 hours.
5.2	Buffer stage (pH 6.8 Phosphate buffer, 1000ml., Paddle, 100 RPM)	Tablet-1 : 101 % Tablet-2 : 100 %	Not less than 75% (Q) of the labeled amount of Pantoprazole (C ₁₆ H ₁₅ F ₂ N ₃ O ₄ S) is dissolved in 45 minutes.

Remarks: APPROVED (Sample Conforms to above Specification)
Stability Specification: ASS-010079 - 1.00

Prepared By	Reviewed By	Approved By
C. Jaisankar	SUNITA JALLAPALLY	PULLEMD V SANKARANATHAN REDDY
25-06-2025 09:56	28-06-2025 11:19	28-06-2025 12:17
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HETERO LABS LIMITED

Unit-V, TSILC Formulation SEZ, S. No. 439,440,441 & 458,
Polepally Village, Jadcherla, Mahaboob Nagar – 509301,
Telangana State, INDIA.



CERTIFICATE OF ANALYSIS

Product Name: PANTO PRAZOLE HETERO;PANTOPRAZOLE 20MG GASTRO RES STANT TABLETS;			
Product Code	4035532	A.C. No.	SSP/2023/03
Specification ID	PPS/3333701-03	Batch No.	P008728
Mfg. Date	10/12/23	Batch Size	370000 Tablets
Exp. Date	03/2025	Date Of Release	23-12-2023 : 007
ReTest Date		Market	UKRAINE

6	Uniformity of Dosage Units (Content Uniformity, By HPLC) (Ph. Eur. 2.8.46, 2.2.29 & In-House; Acceptance value (L1))	Tablet-3 : 99 % Tablet-4 : 99 % Tablet-5 : 99 % Tablet-6 : 99 %/average:99 % n = 2	Not more than 15.0
7	Chromatographic purity (By HPLC) (Ph. Eur. 2.2.29 & In-House;		
7.1	Related compound - D & F	Below LLOD (LOD) = 0.03 % (%w/w)	Not more than 0.5 %w/w
7.2	Related compound - A	0.15 %w/w	Not more than 0.5 %w/w
7.3	Related compound - B	Below LLOD (LOD) = 0.03 % (%w/w)	Not more than 0.2 %w/w
7.4	Any other individual impurity	Below J freque limit (LRL) = 0.05 % w/w	Not more than 0.2 %w/w
7.5	Total impurities	0.15 % w/w	Not more than 1.0 % w/w
8	Assay (By HPLC) (Ph. Eur. 2.2.29 & In-House) Each Gastro-resistant tablet contains		
8.1	Pantoprazole sodium sesquihydrate equivalent to Pantoprazole (C16H15F2N3O4B), in mg	20.43	Not less than 99.0 and Not more than 101.0
8.2	(%) Labeled amount	102.3	Not less than 99.0 and Not more than 101.0
9	Microbiological examination (Ph. Eur. 2.6.12 & 2.6.13)		
9.1	Microbial enumeration tests		
9.1.1	Total aerobic microbial count	Less than 10 cfu per g	Not more than 1000 cfu per g.
9.1.2	Total combined yeast and molds count	Less than 10 cfu per g	Not more than 100 cfu per g.

Remarks: APPROVED (Sample Conforms to above Specification)
Stability Specification: SSP/2023/01-143

Prepared By	Reviewed By	Approved By
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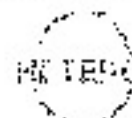
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HETERO LABS LIMITED

Unit-V, TSIC Formulation SEZ, S. No. 439, 440, 441 & 450,
Polapally Village, Jadcherla, Mahabub Nagar – 509301,
Telangana State, INDIA.

**CERTIFICATE OF ANALYSIS**

Product Name: PANTOPRAZOLE HETERO (PANTOPRAZOLE 20MG GASTRO RESISTANT TABLETS)			
Product Code	4035532	A.R. No.	SEFF2501886
Specification ID	FS/33337(1)-03	Batch No.	FJ250125
Mfg. Date	07025	Batch Size	2100000 Tablets
Exp. Date	092027	Date Of Release	23-12-2026 16:17
ReTest Date	-	Market	Local, HL

9.2	Test for specified Microorganisms		
9.2.1	Bile-Tolerant Gram Negative Bacteria	Absent	Should be absent
9.2.2	Escherichia coli	Absent	Should be absent
9.2.3	Salmonella	Absent	Should be absent
9.2.4	Staphylococcus aureus	Absent	Should be absent
9.2.5	Pseudomonas aeruginosa	Absent	Should be absent
10	Identification of colourant (In-House)		
10.1	Titanium dioxide	A pale yellow colour on orange colour develops immediately.	A pale yellow colour to orange colour develops immediately.
10.2	Iron oxide	A red colour develops which does not disappear upon addition of dilute hydrochloric acid	A red colour should develop which does not disappear upon addition of dilute hydrochloric acid.
11	Hardness (In-House)		Not less than 20 Newtons
	Min 181 Newtons Max 194 Newtons		

Reference: APPLICABLE (Sample Lot Number to know specific batch)
Stability Specification: SSS/20137014-02

Prepared By	Reviewed By	Approved By
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