

**URANUS LABORATORIES**2nd FLOOR, H.NO 30, SITARAMPUR 2, NEAR
BY NEW SARASWATI SCHOOL, RAMGARH
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URANUS LABORATORIES

CERTIFICATE OF ANALYSIS (Sample COA)

PAGE NO. 1 of 2

GENERIC NAME	Pancreatin Pellets 67%		
ANALYSIS REPORT NO.	UL/AL/01/2022/001		
BATCH NO.	P12022001	MFG. DATE	JUN-2022
BATCH SIZE/QUANTITY	50.00 KG	EXP. DATE	MAY-2025

SR. NO.	TEST	RESULT	SPECIFICATION	
1.	DESCRIPTION	Light yellow to slight brown coloured pellets.	Light yellow to slight brown coloured pellets.	
2.	IDENTIFICATION			
	TEST A	Complies	Suspension (a) is colourless or slightly pink and suspension (b) is distinctly more red.	
3.	ASSAY			
	A.	Lipase activity	25019 Ph. Eur. units	Not less than 22500 Ph. Eur. Units
	B.	Amylase activity	20192 Ph. Eur. units	Not less than 16200 Ph. Eur. Units
	C.	Protease activity	1285 Ph. Eur. units	Not less than 900 Ph. Eur. Units
4.	DISSOLUTION - ACID FOLLOWED BY BUFFER STAGE	Minimum : 23199 Ph. Eur. Units Maximum : 25279 Ph. Eur. Units Average : 24379 Ph. Eur. Units	Not less than 18750 (Q) Ph. Eur. units of labelled units of lipase activity should be released in 30 minutes in buffer media.	
5.	RESIDUAL SOLVENT			
	A.	ISOPROPYL ALCOHOL	2157 ppm	Not more than 5000 ppm
	B.	DICHLOROMETHANE	Not Detected	Not more than 600 ppm

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6.	ADDITIONAL TEST			
	A.	PARTICLE SIZE	0.26%	Not more than 25% pellets should retain on #12 mesh
			97.10%	Not less than 75% pellets should retain on #20 mesh
	B.	BULK DENSITY	0.75 g/mL	Not less than 0.65 g/ML
	C.	LOSS ON DRYING	2.28% w/w	Not more than 5.0% w/w
7.	A	TOTAL AEROBIC MICROBIAL COUNT	1000 CFU/g	Not more than 10000 CFU/g
	B	TOTAL YEAST AND MOULD COUNT	20 CFU/g	Not more than 100 CFU/g
	TEST FOR SPECIFIED MICROORGANISMS#			
	A	<i>Escherichia coli</i>	absent	Should be absent/g
	B	<i>Salmonella Species</i>	absent	Should be absent/10 g
	C	<i>Pseudomonas aeruginosa</i>	absent	Should be absent/g
	D	<i>Staphylococcus aureus</i>	absent	Should be absent/g

Remark: Electronically generated Certificate of analysis (COA).