

CERTIFICATE OF ANALYSIS

Product: **INTRAMAR LACTO 200 mg + 50 mg + 10 mg, suspensie intramamară**

Batch No.: **045632A**

Expiry: **11/2026**

Date of production: **26.6.2025**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Cream to yellow-brown oily suspension.		conforms
Package extractable volume	2.7 – 3.3 g		2.94 g
Water content	max. 2.5 %		0.13 %
Amoxicillin identity	Rt and UV spectrum match with standard		conforms
Clavulanic acid identity	Rt and UV spectrum match with standard		conforms
Prednisolone identity	Rt and UV spectrum match with standard		conforms
Amoxicillin assay	190.0-210.0 mg/applicator	180.0-210.0 mg/applicator	192.09 mg/applicator
Content of amoxicillin impurities			
- amoxicillin dimer (IMP J)	Max. 4.0 %	Max. 4.0 %	1.8 %
- individual unknown impurity	Max. 1.0 %	Max. 1.0 %	0.5 %
- IMP D	Max. 1.0 %	Max. 1.5 %	<1.0 %
- sum of impurities (without IMP J – dimer)	Max. 2.0 %	Max. 4.0 %	1.52 %
Clavulanic acid assay	47.5-52.5 mg/applicator		50.02 mg/applicator
Content of clavulanic acid impurities			
- individual unknown impurity	Max. 1.0 %		ND
- sum of impurities	Max. 1.0 %		0.00 %
Prednisolone assay	9.5-10.5 mg/applicator		9.59 mg/applicator
Content of prednisolone impurities			
- individual unknown impurity	Max. 1.0 %	Max. 1.0 %	<1.0 %
- sum of impurities	Max. 1.5 %	Max. 2.0 %	0.42 %
Particles size	Min. 10.0 % particles ≤ 10 µm Min. 50.0 % particles ≤ 25 µm Min. 90.0 % particles ≤ 180 µm		37.4 % particles ≤ 10 µm 64.0 % particles ≤ 25 µm 95.8 % particles ≤ 180 µm
Viscosity	50 - 200 mPa.s		101.4 mPa.s
Resuspendability	Must comply.		conforms
Syringeability	Must comply.		conforms
Sterility	Must comply.		conforms

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 567, V001.



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12/08/2025
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HEAD of QC, QP