

CERTIFICATE OF ANALYSIS

Product: **LINEOMAM LC soluție intramamară, 330 mg/10 ml + 100.000 UI/10 ml**Batch No.: **37 60 25 A**Expiry: **01.10.2020**Date of production: **02.10.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	A clear, colourless to yellowish solution, free of visible particles. It is not yellower than reference solution Ž2. The solution is not more opalescent than reference solution I.		conforms
Sterility	The preparation must be sterile.		sterile
Extractable volume	9.0 – 11.0 ml		10.2 ml
Lincomycin hydrochloride identity	Must conform		conforms
Lincomycin base content	313.0 – 347.0 mg / 10 ml		345.80 mg / 10 ml
Neomycin sulfate identity	Must conform		conforms
Neomycin sulfate content	92 000 – 108 000 IU / 10 ml		97 427 IU / 10 ml
Edetane disodium identity	Must conform		conforms
Edetane disodium content	4.05 – 4.95 mg / 10 ml		4.22 mg /10 ml
Purity tests			
Lincomycin hydrochloride	Lincomycin B - max. 6.0 %		3.12 %
	impurity A – max. 0.8 %		0.33 %
	impurity B – max. 0.8 %		0.16 %
	impurity B' – max. 0.6 %		0.00 %
	impurity C – max. 0.6 %		0.51 %
	any individual undefined impurity – max. 0.5 %		0.04 %
Sum of impurities of lincomycin HCl without lincomycin B	max. 3.0 %		1.05 %
Neomycin sulfate	neomycin C – 3.0 – 15.0 %		14.39 %
	neamine – max. 2.0 %		0.00 %
	any individual undefined impurity – max. 5.0 %		< LOQ
Sum of impurities of neomycin sulfate without neomycin C	max. 8.5 %		0.00 %
pH	4.0 – 5.5		4.8
Density	1.01 – 1.05 g/cm ³		1.02 g/cm ³

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. 455.



.....06/11/2018
Mgr. Hana Nezvalová
HEAD of QC, QP