

## CERTIFICATE OF ANALYSIS

Product: **LINEOMAM LC soluție intramamară, 330 mg/10 ml + 100.000 UI/10 ml**

Batch No.: **625629A**

Expiry: **05/2024**

Date of production: **15.6.2022**

### Results of analysis:

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| 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                                                                                                                                                                            |                   | 10.1 ml                                             |
| Lincomycin hydrochloride identity                        | Must conform                                                                                                                                                                             |                   | conforms                                            |
| Lincomycin base content                                  | 313.0 – 347.0 mg / 10 ml                                                                                                                                                                 |                   | 342.51 mg / 10 ml                                   |
| Neomycin sulfate identity                                | Must conform                                                                                                                                                                             |                   | conforms                                            |
| Neomycin sulfate content                                 | 92.000 – 108.000 IU / 10 ml                                                                                                                                                              |                   | 98 844 IU / 10 ml                                   |
| Edetane disodium identity                                | Must conform                                                                                                                                                                             |                   | conforms                                            |
| Edetane disodium content                                 | 4.05 – 4.95 mg / 10 ml                                                                                                                                                                   |                   | 4.57 mg /10 ml                                      |
| Purity tests                                             |                                                                                                                                                                                          |                   |                                                     |
| Lincomycin hydrochloride                                 | Lincomycin B - max. 6.0 %<br>impurity A – max. 0.8 %<br>impurity B – max. 0.8 %<br>impurity B´ – max. 0.6 %<br>impurity C – max. 0.6 %<br>any individual undefined impurity – max. 0.5 % |                   | 3.6 %<br>0.28 %<br>0.17 %<br>ND<br>0.05 %<br><0.5 % |
| Sum of impurities of lincomycin HCl without lincomycin B | max. 3.0 %                                                                                                                                                                               |                   | 0.71 %                                              |
| Neomycin sulfate                                         | neomycin C – 3.0 – 15.0 %<br>neamine – max. 2.0 %<br>any individual undefined impurity – max. 5.0 %                                                                                      |                   | 12.81 %<br>0.00 %<br>ND                             |
| Sum of impurities of neomycin sulfate without neomycin C | max. 8.5 %                                                                                                                                                                               |                   | 0.00 %                                              |
| pH                                                       | 4.0 – 5.5                                                                                                                                                                                |                   | 5.2                                                 |
| Density                                                  | 1.01 – 1.05 g/cm <sup>3</sup>                                                                                                                                                            |                   | 1.015 g/cm <sup>3</sup>                             |

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.



.....13/07/2022  
Mgr. Hana Nezvalová  
HEAD of QC, QP