

CERTIFICATE OF ANALYSIS

Product: **GAMARET, suspensie intramamară**

Batch No.: **51 57 26 A**

Expiry: **01.04.2020**

Date of production: **02.07.2019**

Results of analysis:

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Tests	Release limits	Shelf-life limits	Results
Appearance	Homogenous, low yellowish suspension.		conforms
Content of the original package	min. 10.0 ml		10.5 ml
Sterility	The preparation must be sterile.		sterile
Identity test.:			
Novobiocine	Shall conform.		conforms
Benzylpeniciline Procaine	Shall conform.		conforms
Neomycine	Shall conform.		conforms
Dihydrostreptomycine	Shall conform.		conforms
Prednisolum	Shall conform.		conforms
Assay of:			
Neomycine sulfas	9 690 – 10 710 IU/ml		10 245 IU/ml
Novobiocine	9.50 – 10.50 mg/ml		9.72 mg/ml
Benzylpeniciline Procaine	9.50 – 10.50 mg/ml		10.26 mg/ml
Dihydrostreptomycine sulfas	8 669 – 9581 IU/ml		8 969 IU/ml
Prednisolonum	0.95 – 1.05 mg/ml		1.04 mg/ml
Purity tests:			
Novobiocin impurities			
- decarbamylnovobiocin	≤ 6.0 %		3.60 %
- carbamylnovobiocin	≤ 3.0 %		2.44 %
- any other impurity	≤ 1.0 %		ND
- sum of all impurities	≤ 12.0 %		7.84 %
Neomycin impurities			
-neomycin C	3.0 – 15.0 %		9.470 %
-neamine	≤ 2.0 %		0.58 %
- any individual unknown impurities	≤ 5.0 %		≤5.0 %
- sum of impurities without neomycin C	≤ 15.0 %		1.29 %
Procaine benzylpenicillin impurities			
-impurity A	max 1.0 %		0.32 %
-any individual unknown impurity	max 1.0 %		<1.0 %
-sum of all impurities	max. 5.0 %		3.75 %
Dihydrostreptomycine impurities			
-impurityA,B	≤ 1.0 %		0.125 %/ND
-impurityC	≤ 2.0 %		ND
-any individual unknown impurity	≤ 1.0 %		<1.0 %
-sum of all impurities	≤ 5.0 %		1.37 %
Prednisolone impurities			
-impurity A,B,C, J and F	≤ 1.0 %		0.41%/0.10%/0.05%
			0.02 %/0.03 %
-any individual unknown impurity	≤ 1.0 %		0.53 %
- sum of all impurities	≤ 5.0 %		1.14 %

I certify that this product has been tested in the laboratories of a.s. Bioveta and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN no. 320.



06/08/2019
Mgr. Hana Nezvalová
HEAD of QC