

CERTIFICATE OF ANALYSIS

Product: **MAROPITANT Bioveta 10 mg/ml, soluție injectabilă**Batch No.: **015232A**Expiry: **01/2028**Date of production: **26.2.2025**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, colourless to slightly yellowish solution, free of visible particles. The solution is clear like water R. The solution is colourless or is not more intense than the coloured reference solution Y6.		conforms
Extractable volume	Min. 10.0 ml		10.3 ml
pH	4.1 – 4.7		4.6
Maropitant identity test	Rt and UV spectrum match with standard		conforms
Methylparaben identity test	Rt and UV spectrum match with standard		conforms
Propylparaben identity test	Rt and UV spectrum match with standard		conforms
Maropitant assay	9.50 – 10.50 mg/ml		10.068 mg/ml
Methylparaben assay	1.98 – 2.42 mg/ml		2.284 mg/ml
Propylparaben assay	0.198 – 0.242 mg/ml		0.2250 mg/ml
Purity test:			
- any other individual impurity of maropitant	Max. 1.0 %		0.47 %
- sum of impurities of maropitant	Max. 1.0 %		0.47 %
Sterility	Product must be sterile.		sterile
Airtightness	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. 572,V001.



Hana Nezvalová
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HEAD of QC, QP

16/06/2025