

CERTIFICATE OF ANALYSIS

Product: **XYLAZIN BIO 2%, soluție injectabilă**

Batch No.: **61 51 23 A**

Expiry: **11.01.2018**

Date of production: **12.01.2016**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, colourless solution.		conforms
Content of original package	min. 50 ml		50,5 ml
Injection solution colour test	max. 0.02		0.001
Xylazine identity	It shall be proved.		conforms
Xylazinum base content	18.0 – 22.0 mg/ml		20.22 mg/ml
Methylparaben identity	It shall be proved.		conforms
Methylparaben content	0.9 – 1.0 mg/ml		1.0 mg/ml
Propylparaben identity	It shall be proved.		conforms
Propylparaben content	0.09 – 0.10 mg/ml		0.10 mg/ml
pH	4.5 – 5.5		4.98
Sterility	The preparation must be sterile.		sterile
Airtightness	The vials must be closed hermetically.		conforms
Related substances and impurities			
2,6-dimethylanilin	max. 0.2 %		ND
undefined impurities	max. 0.3 %		ND
sum of impurities	max. 0.5 %		0 %

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. 334, spec.01.



.....07/03/2016
 Mgr. Hana Nezvalová
 HEAD of QC, QP