

CERTIFICATE OF ANALYSIS

Product: **SEDAN 35 mg/ml, gel oral**

Batch No.: **115631B**

Expiry: **05/2026**

Date of production: **20.6.2024**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Transparent, orange-yellow gel		conforms
Content of original package	min. 1.0 ml, 10.0 ml		10.4 ml
Density	1.025 – 1.045 g/cm ³		1.0349 g/cm ³
Loss on drying	87.9 – 97.1 %		88.02 %
Identity of Acepromazine maleate (HPLC)	Must comply.		conforms
Content of Acepromazine base (HPLC)	(33.25 – 36.75) mg/ml		34.500 mg/ml
Identity of methylparaben (HPLC)	Must comply.		conforms
Content of methylparaben (HPLC)	(0.585 – 0.715) mg/ml		0.6307 mg/ml
Identity of propylparaben (HPLC)	Must comply.		conforms
Content of propylparaben (HPLC)	(0.315 – 0.385) mg/ml		0.3416 mg/ml
Impurity content of Acepromazine base (HPLC):			
- Acepromazin S-oxid	Max. 1.0 %		0.23 %
- any individual undefined impurity	Max. 1.0 %		0.17 %
- sum of impurities	Max. 1.5 %		0.050 %
Microbiological safety:			
TAMC	10 ² CFU/ml		<10 CFU/ml
TYMC	10 ¹ CFU/ml		<10 CFU/ml
Absence of <i>Escherichia coli</i>	Absence in 1 ml		absent
Injectability	Must comply.		conforms
pH	5.0 – 6.0		5.6
Viscosity	1000 – 5 000 mPas		2 009 mPas
Weight uniformity of single doses in multidose containers	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. 504,V001.



Mgr. Hana Nezvalová
HEAD of QC, QP

19/12/2024