



CERTIFICATE OF ANALYSIS

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

Batch No.: **145632A**

Expiry: **05/2027**

Date of production: **6.6.2025**

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		10.3 ml
Density				1.025 – 1.045 g/cm ³		1.0347 g/cm ³
Loss on drying				87.9 – 97.1 %		88.01 %
Identity of Acepromazine maleate (HPLC)				Must comply.		conforms
Content of Acepromazine base (HPLC)				(33.25 – 36.75) mg/ml		34.337 mg/ml
Identity of methylparaben (HPLC)				Must comply.		conforms
Content of methylparaben (HPLC)				(0.585 – 0.715) mg/ml		0.6563 mg/ml
Identity of propylparaben (HPLC)				Must comply.		conforms
Content of propylparaben (HPLC)				(0.315 – 0.385) mg/ml		0.3800 mg/ml
Impurity content of Acepromazine base (HPLC):						
- Acepromazin S-oxid				Max. 1.0 %		0.14 %
- any individual undefined impurity				Max. 1.0 %		<1.0 %
- sum of impurities				Max. 1.5 %		0.299 %
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		1 947 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.



15/07/2025
Mgr. Hana Nezvalová
HEAD of QC, QP