

CERTIFICATE OF ANALYSIS

Product: TOP SPOT ON STRONGER 650 mg, solution for application – spot-on for dogs

Batch No.: 87 53 26 B

Expiry: 03.03.2021

Date of production: 04.03.2019

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Yellowish clear liquid.		conforms
Solution volume			
- nominal	min. 1 ml		1.1 ml
- usable	at least 1 ml		
Density	1.05 – 1.1 g/ml		1.087 g/ml
Permethrin identity	Must be proved (HPLC).		conforms
Permethrin content	617.5 – 682.5 mg/ml	585.0 – 682.5 mg/ml	666.74 mg/ml
Impurities			
- individual unspecified impurity	max. 1.0 %		conforms
- sum of impurities	max. 2.5 %		0.66 %
Butylparabene identity	Must be proved (HPLC).		conforms
Butylparabene content	0.95 – 1.05 mg/ml	0.90 – 1.10 mg/ml	1.001 mg/ml
Butylhydroxyanisole identity	Must be proved (HPLC).		conforms
Butylhydroxyanisole content	0.18 – 0.22 mg/ml	0.16 – 0.22 mg/ml	0.200 mg/ml
Butylhydroxytoluene identity	Must be proved (HPLC).		conforms
Butylhydroxytoluene content	0.09 – 0.11 mg/ml	0.08 – 0.11 mg/ml	0.097 mg/ml
Microbiological quality	Must comply. TAMC (CFU/ml): 10^2 TYMC (CFU/ml): 10^1 Absence of Staphylococcus aureus in 1 ml Absence of Pseudomonas aeruginosa in 1 ml		<10 CFU/ml <10 CFU/ml absent absent

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. 375.




09/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP