



## Certificate of Analysis

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<b>Name of Product:</b>	Pestigon 67mg Racepegteto Oldat Kistestu Kutyaknak A.U.V. [Alpha Vet Hungary] 96901-DP1-02(471)			
<b>Batch Number</b>	<b>Quantity</b>	<b>Manufacture Date</b>	<b>Expiry Date</b>	<b>Packaging</b>
4421-503	4,000	October 2014	October 2017	0.67ml Pipette
<b>Active Ingredients:</b>	• Fipronil (100 mg/ml)			
<b>Storage Conditions:</b>	Store in a cool dry place, protected from light.			

Analytical	Results	Specifications
Appearance	Conforms	A clear, colourless to pale yellow liquid.
Fipronil Identification	Confirmed Confirmed	• HPLC retention time compares to that of reference • Maximum UV absorption observed at 280nm
Fipronil Content	66.09 mg/pipette 9.77 %w/v	• 63.65 to 70.35 mg/pipette. • 9.50 to 10.50 %w/v [95 to 105% of nominal mg fipronil/delivered amount based on average deliverable mass]
Water Content	0.35 %	Not more than 1.0 %
Degree of Colouration	Conforms	Not more coloured than reference solution Y4
Clarity and Degree of Opalescence	Conforms	Not more opalescent than reference suspension Y1
Butylhydroxyanisole	Conforms  86 %w/v	• Identification: HPLC retention time compares to that of reference • Content: 70 to 110 %w/v based on average deliverable mass
Butylhydroxytoluene	0.1159 mg/pipette Conforms  98 %w/v	• 0.0938 to 0.1474 mg/pipette. • Identification: HPLC retention time compares to that of reference • Content: 70 to 110 %w/v based on average deliverable mass
Uniformity of Dosage Units	0.0659 mg/pipette Conforms	• 0.0469 to 0.0737 mg/pipette.
Deliverable Volume	Conforms	Meets the current Ph. Eur test requirements (Section 2.9.40)
Microbial Quality	0.677 ml Conforms Conforms Conforms	0.606 to 0.741 ml. • TAMC Count: Not more than 10 <sup>2</sup> cfu per mL • TYMC Count: Not more than 10 <sup>1</sup> cfu per mL • Absence of <i>Staph aureus</i> and <i>Ps aeruginosa</i>

I hereby certify that the above information is authentic and accurate in so far that the specification information is available to us and we confirm that our scientific findings are true. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site (Manufacturing Authorisation Number: ManA 2000) in full compliance with GMP requirements and in accordance with the specification provided to us. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Prepared By:

Wadine Anderson

Date:

19-November-2014

Goods Invoice Number:

APPROVED FOR THE HEAD OF QUALITY CONTROL



Mr Stephen Mitchell B.Sc.  
Director of Technical Compliance  
Qualified Person