

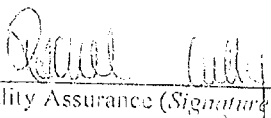
Customer: Ireland

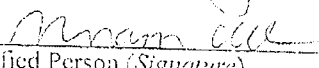
CERTIFICATE OF ANALYSIS / CONFORMANCE

Product:	Animec Super Injection	Man. Date:	07 / 2017
C/N:	1732108	Expiry Date:	06 / 2020
Batch No.:	133368/D	Pack Size:	250ml
		Quantity:	800

Test	Specification	Result
Description:	A clear colourless to slightly yellow coloured solution no darker in colour than PhEur Reference Solution Y. No visible particulates.	Complies
Container / Closure	Intact, no irregularities	Complies
pH	5.0 – 7.0	6.9
Moisture	NMT 0.5%	0.1%
Assay:	9.5 – 10.5 mg / ml	Complies
Ivermectin Content B _{1a} and B _{1b}	95 – 105% of L.C. Ivermectin B _{1a} is ≥ 90% of total Ivermectin B _{1a} + Ivermectin B _{1b}	9.6mg / ml 97.7% of L.C.
Identification – Ivermectin	1. Retention times of the two principal peaks in sample chromatogram correspond to that of standard chromatogram. 2. R _f of the sample corresponds to the R _f for the ivermectin standard.	Complies Complies
Impurities: Individual RT 1.3 – 1.5 Any other individual Total	NMT 2.5% of Ivermectin B _{1a} + Ivermectin B _{1b} peak area NMT 1% of Ivermectin B _{1a} + Ivermectin B _{1b} peak area NMT 5.0% of Ivermectin B _{1a} + Ivermectin B _{1b} peak area	H ₂ B ₁ Isomer 1.1% Ivermectin B _{1a} & B _{1b} 0.3% Total: 2.3%
Assay: Clorsulon	95.0 – 105.0 mg / ml	101.5mg / ml Complies
Identification – Clorsulon	1. Retention times of the two principal peaks in sample chromatogram correspond to that of standard chromatogram. 2. R _f of the sample corresponds to the R _f for the clorsulon standard.	Complies Complies
Related Substances -Clorsulon	Individual impurity: NMT 0.5% Total Impurities: NMT 2.0%	<0.3% <0.3%
Fill Check	NLT claimed volume	252-254 ml
Sterility	Must comply to Ph. Eur.	Complies

The above material conforms to the required specification as transcribed from the Manufacturer's Certificate of Analysis and is approved for use. The manufacturing, packaging and testing of the above batch was carried out in accordance with GMP and the relevant Marketing Authorisation No. VPA 10987/68/1. The product is fit for use and may be released to the market.

Checked By:  Date: 07/07/17
Quality Assurance (Signature)

Approved By:  Date: 07/07/17
Qualified Person (Signature)

MICHAEL H BURKE
Qualified Person (Print Name)