

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Animec Super Injection
C/N: 1627066
Batch No.: K32507/A
Man. Date: 06 / 2016
Expiry Date: 05 / 2019
Pack Size: 250ml

Test	Specification	Result
Description:	A clear colourless to slightly yellow coloured solution no darker in colour than PhEur Reference Solution Y ₁ . No visible particulates.	Complies
Container / Closure	Intact, no irregularities	Complies
pH	5.0 – 7.0	6.5 Complies
Moisture	NMT 0.5%	0.1% Complies
Assay: Ivermectin Content B _{1a} and B _{1b}	9.5 – 10.5 mg / ml 95 – 105% of L.C. Ivermectin B _{1a} is ≥ 90% of total Ivermectin B _{1a} + Ivermectin B _{1b}	9.7mg / ml 98.2% of L.C. Complies
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 _{1a} Isomer 1.0% Ivermectin B _{1a} & B _{1b} 0.3% Total: 1.6%
Assay: Clorsulon	95.0 – 105.0 mg / ml	96.6mg / 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	Individual impurity: NMT 0.5% Total Impurities: NMT 2.0%	<0.3% <0.3%
Fill Check	NLT claimed volume	250.0 – 250.0ml
Sterility	Must comply to Ph. Eur.	Complies

The above material conforms to the required specification as transcribed from the Manufactures 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: [Signature] Date: 06/06/16
Quality Assurance (Signature)

Approved By: [Signature] Date: 11/06/16
Qualified Person (Signature)

YVONNE EBYN
Qualified Person (Print Name)