

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Animec Super Injection
C/N: 1732108
Batch No.: 133368/D ✓

Man. Date: 07 / 2017
Expiry Date: 06 / 2020
Pack Size: 250ml
Quantity: 1,300

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	6.9 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}	9.5mg / ml 97.7% 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 ₁ B _{1a} isomer 1.1% Ivermectin B _{1a} & B _{1b} 0.3% Total: 2.3%
Assay: Clorsulon	95.0 – 105.0 mg / ml	101.4mg / 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 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: *Rachel Cully* Date: 9/3/18
Quality Assurance (Signature)

Approved By: *Miriam Hill* Date: 9/3/18
Qualified Person (Signature)

Miriam Hill
Qualified Person (Print Name)

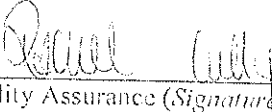
Customer: Ireland

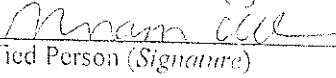
CERTIFICATE OF ANALYSIS / CONFORMANCE

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 ₁ . No visible particulates.	Complies
Container / Closure	Intact, no irregularities	Complies
pH	5.0 – 7.0	6.9 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}	9.6mg / ml 97.7% 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 1.1% Ivermectin B _{1b} & B _{1a} 0.3% Total: 2.3%
Assay: Clorsulon	95.0 – 105.0 mg / ml	101.4mg / 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

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Checked By:  Date: 07/03/18
Quality Assurance (Signature)

Approved By:  Date: 07/03/18
Qualified Person (Signature)

Miriam Kelly
Qualified Person (Print Name)

Customer: Ireland

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Animec Super Injection Man. Date: 07 / 2017
C/N: 1732108 Expiry Date: 06 / 2020
Batch No.: 133368 Pack Size: 350ml

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	6.9 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}	9.6mg / ml 97.7% 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 ₁ B _{1a} Isomer 1.1% Ivermectin B _{1a} & B _{1b} 0.3% Total: 2.3%
Assay: Clorsulon	95.0 – 105.0 mg / ml	101.4mg / 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%	<0.5% <0.3%
Fill Check	NLT claimed volume	252-254ml
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: Roche Kelly
Quality Assurance (Signature)

Date: 26/09/17

Approved By: Anne Kelly
Qualified Person (Signature)

Date: 28/09/2017

Anne Kelly
Qualified Person (Print Name)