chanelle
PHARMACEUTICALS
MANUFACTURING LTD
Customer: Ireland

Chanelle Pharmaceuticals Manufacturing Ltd.,
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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:	1,300

Test	Specification	Result
Description:	A clear colourless to slightly yellow coloured solution no darker in colour than PhEur Reference Solution Y_6. 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_2B_{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: _____ Date: 8/3/18
Quality Assurance (*Signature*)

Approved By: _____ Date: 8/03/2018
Qualified Person (*Signature*)

_____
Qualified Person (*Print Name*)

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Web: www.chanellegroup.ie

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_7. 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. Rf of the sample corresponds to the Rf 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_2B_{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. Rf of the sample corresponds to the Rf 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: 6/6/18
Quality Assurance (*Signature*)

Approved By: _____ Date: 6/6/18
Qualified Person (*Signature*)

Miriam Horwath
Qualified Person (*Print Name*)

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Web: www.chanellegroup.ie

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:	250ml

Test	Specification	Result
Description:	A clear colourless to slightly yellow coloured solution no darker in colour than PhEur Reference Solution Y_7. 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
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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_2B_{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
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Related Substances	Individual impurity: NMT 0.5% Total Impurities: NMT 2.0%	<0.5% <0.5%
Fill Check	NLT claimed volume	252-254ml
Sterility	Must comply to Ph. Eur.	Complies

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The product is fit for use and may be released to the market.

Checked By: _____ Date: 4/09/19
Quality Assurance (*Signature*)

Approved By: _____ Date: 25/09/2019
Qualified Person (*Signature*)

Anne Kelly
Qualified Person (*Print Name*)