Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea, Co. Galway, Ireland.
Tel: +353 (0)91 841788
Fax: +353 (0)91 842937
www.chanellepharma.com

CERTIFICATE OF ANALYSIS / CONFORMANCE

Product: Chanhold 60mg/ml 15mg 0.25ml x 3's	**Man Date:**	**04/2021**
Customer: Orion	**Expiry Date:**	**03/2024**
Livery: HU	**Quantity:**	**401 x 3's**
Bulk Batch No.: 21045	**Packing Batch No.:**	**21045B/1**
Manufacturing Licence No. V12240/00001		

TESTS	SPECIFICATIONS	RESULT
Appearance	Clear, colourless to yellow solution.	Complies
Condition of packaging	No evidence of breakage or leakage	Complies
Moisture	≤ 1.5%	0.26%
Identification Selamectin (HPLC/UV)	(a) Retention time: The assay chromatogram obtained from the sample shows a peak with the same retention time as the principal peak in the chromatogram obtained with the standard. (b) UV spectrum: The UV spectrum obtained for the sample is compared to the peak area of the standard.	(a) Complies (b) Complies
Identification: Butylhydroxytoluene	The chromatography of the HPLC assay exhibits a major peak due to butylhydroxytoluene the retention time of which is comparable to that exhibited in the chromatogram of the standard.	Complies
Assay: Selamectin	15 mg/pipette ± 5% i.e. (14.25 – 15.75 mg/pipette)	15.36mg
Assay: Butylhydroxytoluene	0.18 – 0.22 mg/pipette.	0.20mg
Selamectin Impurity A	≤ 2.0%	0.097%
Selamectin Impurity B	≤ 2.0%	<LOD
Selamectin Impurity C	≤ 1.5%	<LOD
Selamectin Impurity D	≤ 1.5%	0.037%
Individual impurities	≤ 1.0%	0.364%, 0.307%, 0.348%
Selamectin Total impurities:	≤ 4.0%	1.15%
Uniformity of dosage unit (by mass variation)	The acceptance value of the first 10 dosage units is less than or equal to L1. If the acceptance value is greater than L1, test the next 20 dosage units and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to L1 and no individual content of the dosage unit is less than (1-L2x0.01) M or more than (1+L2x0.01) M unless otherwise specified. L1 is 15.0 and L2 is 25.0. PhEur 2.9.40.	Selamectin Av 5.79
Seal integrity test	No leaks observed	Complies
Microbial Purity*	Total Aerobic Microbial Count NMT 10^2 CFU/g Total Yeast/Moulds Microbial Count NMT 10^1 CFU/g Absence of S. aureus & P. aeruginosa	Non routine Test

*This is a non-routine test conducted on one in every 10 batches manufactured.
Results have been transcribed from Realoch Pharma Certificate of Analysis/Conformance.

This product has been manufactured, analysed and packaged in accordance with the relevant Marketing Authorisation No. EU/2/19/236/001.
There were no deviations associated with the above batch. The product is fit for use and may be released for sale to Market.

Checked By: _____ Date: 14/06/2021
Quality Assurance (Signature)

Approved By: _____ Date: 15/06/2021
Qualified Person (Signature)

_____
Qualified Person (Print Name)