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## CERTIFICATE OF ANALYSIS / CONFORMANCE

| | | |
|---|---|---|
| **Product: Chanhold 60mg/ml 45mg x 3's** | **Man Date:** | **11/2020** |
| **Customer: Orion** | **Expiry Date:** | **10/2022** |
| **Livery: HU / PL** | **Quantity:** | **550 x 3's** |
| **Bulk Batch No.: 20092** | **Packing Batch No.:** | **20092F/2** |
| **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 | NMT 1.5% | 0.28% |
| 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.<br>(b) UV spectrum: The UV spectrum obtained for the sample is compared to the peak area of the standard | (a) Complies<br>(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 | 45 mg/pipette ± 5% i.e. (42.75 – 47.25 mg/pipette) | 45.73mg |
| Assay: Butylhydroxytoluene | 0.54 - 0.66 mg/pipette | 0.59mg |
| Selamectin Impurity A | NMT 2.0% | 0.106% |
| Selamectin Impurity B | NMT 2.0% | 0.251% |
| Selamectin Impurity C | NMT 1.5% | < LOD |
| Selamectin Impurity D | NMT 1.5% | 0.018% |
| Individual impurities | NMT 1.0% | 0.537% |
| Selamectin Total impurities | NMT 4.0% | 1.287% |
| 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 0.87 |
| 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

This product has been manufactured, analysed and packaged in accordance with the relevant Marketing Authorisation No EU/2/19/236/003. There were no deviations associated with the above batch. Results have been transcribed from Realoth Pharma Certificate of Analysis/Conformance. The product is fit for use and may be released for sale to Market.

**Checked By:** _____ Date: 06/01/2021
Quality Assurance (Signature)

**Approved By:** _____ Date: 06/01/2021
Qualified Person (Signature)

_____
Qualified Person (Print Name)