Veterinary Medicines Directorate

Certificate No: VMDGMP/M0147/2022

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

UK Manufacturer

Part 1

Issued following an inspection in accordance Schedule 2 of the Veterinary Medicines Regulations 2013 as it has effect in Northern Ireland and Great Britain.

The competent authority of: UNITED KINGDOM (***Veterinary***) confirms the following:

The manufacturer: **Dales Pharmaceuticals Limited**

Site address: Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA123** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **23rd to 27th May 2022**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice as required by the Veterinary Medicines Regulations 2013.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified on EudraGMP or on GOV.UK If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 04 October 2023

Name: CONFIDENTIAL

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: 1.1.2.1 Large volume liquids Special Requirements: Other - An injectable suspension which contains active pharmaceutical ingredient that replace the hormone deficiency in dogs. 1.1.2.2 Semi-solids 1.1.2.3 Small volume liquids Special Requirements: Other - An injectable suspension which contains active pharmaceutical ingredient that replace the hormone deficiency in dogs. 1.1.3 Batch certification
1.2	Non-sterile products: 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.17 Other non-sterile medicinal products Including active pharmaceutical ingredient which balance the level of hormones in dogs & cats 1.2.2 Batch certification
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: 1.4.2 Sterilisation of active substances/excipients/finished products 1.4.2.3 Moist heat
1.5	Packaging only: 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.2 Secondary packing
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

2.	IMPORTATION OF MEDICINAL PRODUCTS
2.1	Quality control testing of imported medicinal products N/A
2.2	Batch certification of imported medicinal products N/A

Any restrictions or clarifying remarks related to the scope of this certificate:

The repackaging and distribution of Trilostan (active substance for veterinary and human use) was covered during the latest inspection and therefore these activities are covered by this certificate

Name and signature of the authorised person of the Competent Authority of the UK:

Signature: CONFIDENTIAL

Date: 04 October 2023

Name: CONFIDENTIAL