



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with 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: **Wellmark International (Central Life Sciences)**

Site address: 12111 Ford Road
Dallas
Texas 75234
United States of America

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the United Kingdom in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **23 March 2023**, 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 in EudraGMP or on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 23 May 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

The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food and Rural Affairs



Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: Not applicable
1.2	Non-sterile products: 1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.4 Impregnated matrices 1.2.1.5 Liquids for external use
1.3	Biological medicinal products: Not applicable
1.4	Other products or manufacturing activity: Not applicable
1.5	Packaging: 1.5.1 Primary packing 1.5.1.4 Impregnated matrices 1.5.1.5 Liquids for external use
1.6	Quality Control testing: 1.6.3 Chemical/Physical

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

This certificate covers:

- Apistan manufacture (tau fluvalinate impregnated PVC strips for *varroa* mite control in bee-hives).
- Manufacture of liquid spot-on ectoparasiticide products.

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

CONFIDENTIAL

Signature: _____

Date: 23 May 2023

Name: CONFIDENTIAL