Veterinary Medicines Directorate

Certificate No: VMDGMP/M163/2023

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: **Inovat Indústria Farmacêutica Ltda**

Site address: Presidente Tancredo de Almeida Neves 1555
CEP: 07112-070
Guarulhos
Sao Paulo
Brazil

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 **29th November to 2nd December 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 GOV.UK. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 27th February 2023

Name: CONFIDENTIAL

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911 Fax +44 (0)1932 336618
Search for VMD on GOV.UK

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: 1.1.1 Aseptically prepared 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging: 1.5.2 Secondary packaging
1.6	Quality Control testing: 1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/physical

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

1. This certificate covers the manufacture of aseptically prepared sterile liquid products and terminally sterilised products where the aseptic filling process is followed by sterilisation in an autoclave.
2. With the exception of raw material dispensing, the production operations covered by this certificate (i.e. solution formulation, filtration, filling and packaging) are performed in building 203.
3. Although a number of other manufacturing operations occur at the site, these were not inspected and thus are not covered by this certificate.

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

Signature: CONFIDENTIAL

Name: CONFIDENTIAL

CONFIDENTIAL
CONFIDENTIAL

Date: 27th February 2023