Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 53174 Insp IMP 53174/19385617-0004[I]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : REACTA BIOTECH LIMITED T/A REACTA HEALTHCARE

Site address : REACTA BIOTECH LIMITED T/A REACTA HEALTHCARE, 2 NEWTECH SQUARE, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NT, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 53174 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 01/11/2022 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.11] Semi-solids

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

Restrictions or Remarks

Secondary packaging operations restricted to open label, non-randomised activities associated with Non-IMPs / Auxiliary Medicinal Products for use as challenge agents in clinical trials.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
				Limited to manufacture and assembly of Non-IMPs / Auxiliary Medicinal Products for use as challenge agents in clinical trials.

18/01/2023 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

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Tel : Confidential