Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 40676 Insp GMP 40676/5124258-0010 [H]

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

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : ADM PROTEXIN LIMITED

Site address : ADM PROTEXIN LIMITED, LOPENHEAD, SOUTH PETHERTON, TA13 5JH, UNITED KINGDOM
Other :
Desk-based assessment, to review site compliance information, in order to issue a new GMP certificate.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 14/03/2025, 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 Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile products

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

[1.2.1.1] Capsules, hard shell

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products
Sachets - Pastes

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products
Microbiological (probiotic)

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products
Sachets, pastes

[1.5.2] Secondary packaging

Restrictions or Remarks

This GMP certificate covers manufacture for export to MRA countries, in which probiotics are classified as medicines. Operations in the QC laboratory included in the scope of this GMP Certificate are limited to the enumeration of probiotics only.
This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/re
gistration. A risk-based site inspection programme remains in force.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Inspection included a satellite storage site at Ilton Business Park as well as the buildings at the main site at Lopen Head.				

14/03/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential