

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 50506

2: Name of authorisation holder BESPAK HC LIMITED

3: Address(es) of manufacturing site(s) BESPAK HC LIMITED, LONDON ROAD, HOLMES CHAPEL, CREWE, CW4 8BE, UNITED KINGDOM

4: Legally registered address of authorisation holder BESPAK HC LIMITED, LONDON ROAD, HOLMES CHAPEL, CREWE, CW4 8BE, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 28/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BESPAK HC LIMITED, LONDON ROAD, HOLMES CHAPEL, CREWE, CW4 8BE, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms [1.2.1.9] Pressurised preparations [1.5] Packaging [1.5.1] Primary packaging [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical