

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

09/02/2026

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

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA