

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	01/05/2024
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