

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	22/01/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.1.9] Pressurised preparations [1.2.1.15] Other non-sterile medicinal products Dry powder inhalers, Metered dose inhalers. [1.5] Packaging [1.5.1] Primary packaging [1.5.1.6] Liquids for internal use [1.5.1.9] Pressurised preparations

[1.5.1.15] Other non-sterile medicinal products

Dry powder inhalers, Metered dose inhalers

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical