

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 50506  |
| <b>2: Name of authorisation holder</b>  | BESPAK HC LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | BESPAK HC LIMITED, LONDON ROAD, HOLMES CHAPEL, CREWE, CW4 8BE, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | BESPAK HC LIMITED, LONDON ROAD, HOLMES CHAPEL, CREWE, CW4 8BE, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)          |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential  |
| <b>8: Authorisation Date</b>  | 01/05/2024  |
| <b>9: Annexes attached</b>  | 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)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.6 ] Liquids for internal use<br>[ 1.2.1.8 ] Other solid dosage forms<br>[ 1.2.1.9 ] Pressurised preparations<br><b>[ 1.5 ] Packaging</b><br>[ 1.5.1 ] Primary packaging<br>[ 1.5.1.6 ] Liquids for internal use<br>[ 1.5.1.8 ] Other solid dosage forms<br>[ 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

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MHRA-GMDP

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