

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|                                                                                                                           |                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| 1: Authorisation Number                                                                                                   | UK MIA(IMP) 12862                                                                                                           |
| 2: Name of authorisation holder                                                                                           | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED                                                                          |
| 3: Address(es) of manufacturing site(s)                                                                                   | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED,<br>NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,<br>UNITED KINGDOM |
| 4: Legally registered address of authorisation holder                                                                     | RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED,<br>DANSOM LANE, KINGSTON-UPON-HULL, HU8 7DS, UNITED<br>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<br>2004 [SI 2004/1031]                                  |
| 7: Name of responsible officer of the competent authority of<br>the member state granting the manufacturing authorisation | Confidential                                                                                                                |
| 8: Authorisation Date                                                                                                     | 09/05/2025                                                                                                                  |
| 9: Annexes attached                                                                                                       | Annex 1 and/or Annex 2                                                                                                      |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED**, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,  
UNITED KINGDOM

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Investigational Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.1 ] Large volume liquids<br>[ 1.1.1.4 ] Small volume liquids<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.8 ] Other solid dosage forms |

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Medicated Lozenges

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical