

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 13581

**2: Name of authorisation holder** NOVA LABORATORIES LIMITED

**3: Address(es) of manufacturing site(s)** NOVA LABORATORIES LIMITED, MARTIN HOUSE,  
GLOUCESTER CRESCENT, WIGSTON, LE18 4YL, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** NOVA LABORATORIES LIMITED, MARTIN HOUSE,  
GLOUCESTER CRESCENT, WIGSTON, LE18 4YL, 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** 18/06/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**NOVA LABORATORIES LIMITED**, MARTIN HOUSE, GLOUCESTER CRESCENT, WIGSTON, LE18 4YL, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids [ 1.1.1.5 ] Solids and implants [ 1.1.1.6 ] Other aseptically prepared products Dry Powders. Spray dried powder. <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.6 ] Liquids for internal use

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.3 ] Cell therapy products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

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

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.11 ] Semi-solids

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological