

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 13581
<b>2: Name of authorisation holder</b>	NOVA LABORATORIES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	NOVA LABORATORIES LIMITED, MARTIN HOUSE / EDWIN HOUSE, GLOUCESTER CRESCENT, WIGSTON, LE18 4YL, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NOVA LABORATORIES LIMITED, MARTIN HOUSE / EDWIN HOUSE, GLOUCESTER CRESCENT, WIGSTON, LE18 4YL, 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>	15/03/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.1 ] Sterile Products

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.4 ] Small volume liquids

##### [ 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

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological medicinal products**

- [ 1.3.1 ] Biological medicinal 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 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
  - [ 1.5.1.6 ] Liquids for internal use
- [ 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