

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 13581

2: Name of authorisation holder NOVA LABORATORIES LIMITED

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

4: Legally registered address of authorisation holder NOVA LABORATORIES LIMITED, MARTIN HOUSE / EDWIN 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 Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 15/03/2024

9: Annexes attached 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