

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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|---|---|
| 1: Authorisation Number | UK MIA(IMP) 12882 |
| 2: Name of authorisation holder | EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST |
| 3: Address(es) of manufacturing site(s) | IPSWICH HOSPITAL, PHARMACY MANUFACTURING UNIT, HEATH ROAD, IPSWICH, IP4 5PD, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, COLCHESTER GENERAL HOSPITAL, TURNER ROAD, COLCHESTER, CO4 5JL, 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 | 26/05/2023 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

IPSWICH HOSPITAL, PHARMACY MANUFACTURING UNIT, HEATH ROAD, IPSWICH, IP4 5PD, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.1] Large volume liquids [1.1.1.4] Small volume liquids [1.1.2] Terminally Sterilised (processing operations for the following dosage forms) [1.1.2.1] Large volume liquids [1.1.2.3] Small volume liquids [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) |

- [1.2.1.1] Capsules, hard shell
- [1.2.1.5] Liquids for external use
- [1.2.1.6] Liquids for internal use
- [1.2.1.11] Semi-solids

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.1] Filtration
 - [1.4.2.2] Dry heat
 - [1.4.2.3] Moist heat

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.2] Capsules, soft shell
 - [1.5.1.5] Liquids for external use
 - [1.5.1.6] Liquids for internal use
 - [1.5.1.11] Semi-solids
 - [1.5.1.12] Suppositories
 - [1.5.1.13] Tablets
 - [1.5.1.15] Other non-sterile medicinal products
 - Powders
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical