

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 12893
2: Name of authorisation holder	UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	PRODUCTION - UNIVERSITY HOSPITALS BRISTOL & WESTON NHS FOUNDATION TRUST, BRISTOL ROYAL INFIRMARY, MARLBOROUGH STREET, BRISTOL, BS2 8HW, UNITED KINGDOM
4: Legally registered address of authorisation holder	UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, KING EDWARD BUILDING, BRISTOL ROYAL INFIRMARY, MARLBOROUGH STREET, BRISTOL, BS2 8HW, 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	24/08/2022
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PRODUCTION - UNIVERSITY HOSPITALS BRISTOL & WESTON NHS FOUNDATION TRUST, BRISTOL ROYAL INFIRMARY, MARLBOROUGH STREET, BRISTOL, BS2 8HW, UNITED KINGDOM

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 [1.2] 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
- [1.2.1.8] Other solid dosage forms
- [1.2.1.11] Semi-solids
- [1.2.1.12] Suppositories

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.4] Gene therapy products

[1.5] Packaging

- [1.5.2] Secondary packaging

[1.6] Quality control testing

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