Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA(IMP) 12893 1: Authorisation Number

UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION 2: Name of authorisation holder

TRUST

PRODUCTION - UNIVERSITY HOSPITALS BRISTOL & WESTON NHS 3: Address(es) of manufacturing site(s)

FOUNDATION TRUST, BRISTOL ROYAL INFIRMARY, MARLBOROUGH

STREET, BRISTOL, BS2 8HW, UNITED KINGDOM

UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION

4: Legally registered address of authorisation 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

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 6: Legal Basis of authorisation

2004/1031]

7: Name of responsible officer of the competent

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 22/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

holder

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

Issue Date: 22 Oct 2025

[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

[1.3] 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

