Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 32485
2: Name of authorisation holder	BELFAST HEALTH AND SOCIAL CARE TRUST
3: Address(es) of manufacturing site(s)	THE PLENUM BUILDING, VICTORIA PHARMACEUTICALS AND REGIONAL QUALITY ASSURANCE SERVICE, ROYAL GROUP OF HOSPITALS SITE, GROSVENOR ROAD, BELFAST, BT12 6BA, UNITED KINGDOM
4: Legally registered address of authorisation holder	BELFAST HEALTH AND SOCIAL CARE TRUST, FIRST FLOOR, KING EDWARD BUILDING, THE ROYAL HOSPITALS, GROSVENOR ROAD, BELFAST, BT12 6BA, 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	18/11/2021
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

THE PLENUM BUILDING, VICTORIA PHARMACEUTICALS AND REGIONAL QUALITY ASSURANCE SERVICE, ROYAL GROUP OF HOSPITALS SITE, GROSVENOR ROAD, BELFAST, BT12 6BA, 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

[1.1.3] Batch certification

[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

[1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] 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

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[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