

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 13523

**2: Name of authorisation holder** STOCKPORT NHS FOUNDATION TRUST

**3: Address(es) of manufacturing site(s)** STOCKPORT PHARMACEUTICALS PRODUCTION UNIT,  
STEPPING HILL HOSPITAL, STOCKPORT, SK2 7JE, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** STOCKPORT NHS FOUNDATION TRUST, STEPPING HILL  
HOSPITAL, POPLAR GROVE, STOCKPORT, SK2 7JE, 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** 19/07/2022

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**STOCKPORT PHARMACEUTICALS PRODUCTION UNIT, STEPPING HILL HOSPITAL, STOCKPORT, SK2 7JE, 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
- [ 1.1.2 ] 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

[ 1.2.1.8 ] Other solid dosage forms

**[ 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

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging