

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| 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,<br>STEPPING HILL HOSPITAL, STOCKPORT, SK2 7JE, UNITED<br>KINGDOM    |
| 4: Legally registered address of authorisation holder   | STOCKPORT NHS FOUNDATION TRUST, STEPPING HILL<br>HOSPITAL, POPLAR GROVE, STOCKPORT, SK2 7JE, UNITED<br>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)<br>Regulations 2004 [SI 2004/1031]                     |
| 7: Name of responsible officer of the competent authority of<br>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**

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

[ 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