

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|                                                                                                                        |                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| 1: Authorisation Number                                                                                                | UK MIA 101                                                                                                                                |
| 2: Name of authorisation holder                                                                                        | NOVARTIS PHARMACEUTICALS UK LIMITED                                                                                                       |
| 3: Address(es) of manufacturing site(s)                                                                                | NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder                                                                  | NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM |
| 5: Scope of authorisation and dosage forms                                                                             | ANNEX 1 and/ or ANNEX 2                                                                                                                   |
| 6: Legal Basis of authorisation                                                                                        | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)                                                                      |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Confidential                                                                                                                              |
| 8: Authorisation Date                                                                                                  | 24/06/2026                                                                                                                                |
| 9: Annexes attached                                                                                                    | Annex 1 and/or Annex 2                                                                                                                    |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**NOVARTIS PHARMACEUTICALS UK LIMITED**, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                                                                                                                              |
| Authorised Operations                                                                                                                                                                                                                                                 |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                             |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br><b>[ 1.3 ] Biological medicinal products</b><br>[ 1.3.2 ] Batch certification |

[ 1.3.2.5 ] Biotechnology products

## Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

### **[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.3 ] Cell therapy products

[ 2.2.3.4 ] Gene therapy products

### **[ 2.3 ] Other Importation Activities**

[ 2.3.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Ordering and Invoicing of all products, including those imported from outside of the EEA