

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 101
<b>2: Name of authorisation holder</b>	NOVARTIS PHARMACEUTICALS UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NOVARTIS PHARMACEUTICALS UK LIMITED, 2ND FLOOR, THE WEST WORKS BUILDING, WHITE CITY PLACE, 195 WOOD LANE, LONDON, W12 7FQ, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	07/12/2023
<b>9: Annexes attached</b>	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

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