

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 3070
<b>2: Name of authorisation holder</b>	IPSEN BIOPHARM LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, 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>	02/06/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, 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>
[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
[ 1.1.1.2 ] Lyophilisates
[ 1.1.1.4 ] Small volume liquids
[ 1.1.3 ] Batch certification
<b>[ 1.3 ] Biological medicinal products</b>
[ 1.3.1 ] Biological medicinal products
[ 1.3.1.5 ] Biotechnology products

**[ 1.4 ] Other products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 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

[ 1.6.4 ] Biological

**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

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing