Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 3070
2: Name of authorisation holder	IPSEN BIOPHARM LIMITED
3: Address(es) of manufacturing site(s)	IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, UNITED KINGDOM
4: Legally registered address of authorisation holder	IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, 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	13/11/2026
9: Annexes attached	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)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[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

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

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[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

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