Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	28/03/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

IPSEN BIOPHARM LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, LL13 9UF, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal 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

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[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

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list

Any restrictions or clarifying remarks

The QPs Mrs Sandrine Weisse, Mrs Tiphaine Lefevre & Mr Adel Ouelhadj are included on this licence solely for the oversight of imported IMPs following certification in an approved country in accordance with the provisions of Regulation 43(1) of UK SI 2004/1031 (as amended). Mrs Sandrine Weisse, Mrs Tiphaine Lefevre & Mr Adel Ouelhadj may not undertake QP certification of other activities performed under this MIA(IMP).