

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 15134

2: Name of authorisation holder OWEN MUMFORD LIMITED

3: Address(es) of manufacturing site(s) OWEN MUMFORD LIMITED, PRIMSDOWN INDUSTRIAL ESTATE, WORCESTER ROAD, CHIPPING NORTON, OX7 5XP, UNITED KINGDOM

4: Legally registered address of authorisation holder OWEN MUMFORD LIMITED, BROOK HILL, WOODSTOCK, OX20 1TU, 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 11/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

OWEN MUMFORD LIMITED, PRIMSDOWN INDUSTRIAL ESTATE, WORCESTER ROAD, CHIPPING NORTON, OX7 5XP, 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 [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.15] Other non-sterile medicinal products Combination Adrenaline autoinjector [1.5] Packaging [1.5.1] Primary packaging

[1.5.1.15] Other non-sterile medicinal products

The combination autoinjector is assembled, labelled and packed by Owen Mumford Ltd. The bulk sterile prefilled syringe is supplied separately and is assembled into the combination product using in-house manufactured plastic components

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing