

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 39820

2: Name of authorisation holder MEXICHEM UK LIMITED

3: Address(es) of manufacturing site(s) KOURA, THORNTON SCIENCE PARK, POOL LANE, INCE, CHESTER, CH2 4NU, UNITED KINGDOM

4: Legally registered address of authorisation holder MEXICHEM UK LIMITED, THE HEATH BUSINESS AND TECHNICAL PARK, RUNCORN, WA7 4QX, 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 03/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

KOURA, THORNTON SCIENCE PARK, POOL LANE, INCE, CHESTER, CH2 4NU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.9] Pressurised preparations [1.5] Packaging [1.5.1] Primary packaging [1.5.1.9] Pressurised preparations [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical