

# 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** 20/11/2024

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.9 ] Pressurised preparations <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging [ 1.5.1.9 ] Pressurised preparations [ 1.5.2 ] Secondary packaging <b>[ 1.6 ] Quality control testing</b> [ 1.6.3 ] Chemical/Physical