

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 18351

2: Name of authorisation holder ALCURA UK LIMITED

3: Address(es) of manufacturing site(s) ALCURA UK LIMITED, ALCURA HOUSE, CASWELL ROAD, BRACKMILLS INDUSTRIAL ESTATE, NORTHAMPTON, NN4 7PU, UNITED KINGDOM

4: Legally registered address of authorisation holder ALCURA UK LIMITED, ALCURA HOUSE, CASWELL ROAD, BRACKMILLS INDUSTRIAL ESTATE, NORTHAMPTON, NN4 7PU, 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 06/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALCURA UK LIMITED, ALCURA HOUSE, CASWELL ROAD, BRACKMILLS INDUSTRIAL ESTATE, NORTHAMPTON, NN4 7PU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.3] Other Importation Activities [2.3.1] Site of Physical Importation [2.3.4] Other Importation of QP certified IMPs from a country on the 'approved country for import list'/Returns and destruction of IMPs