

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 30619

2: Name of authorisation holder CLINUVEL (UK) LIMITED

3: Address(es) of manufacturing site(s) CLINUVEL (UK) LIMITED, WESLEY HOUSE, BULL HILL, LEATHERHEAD, KT22 7AH, UNITED KINGDOM

4: Legally registered address of authorisation holder CLINUVEL (UK) LIMITED, DEVONSHIRE HOUSE, 60 GOSWELL ROAD, LONDON, EC1M 7AD, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 29/06/2018

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CLINUVEL (UK) LIMITED, WESLEY HOUSE, BULL HILL, LEATHERHEAD, KT22 7AH, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.3] Other Importation Activities [2.3.2] Importation of Intermediate which undergoes further processing