

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 30619  |
| <b>2: Name of authorisation holder</b>  | CLINUVEL (UK) LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | CLINUVEL (UK) LIMITED, WESLEY HOUSE, BULL HILL,<br>LEATHERHEAD, KT22 7AH, UNITED KINGDOM      |
| <b>4: Legally registered address of authorisation holder</b>  | CLINUVEL (UK) LIMITED, DEVONSHIRE HOUSE, 60<br>GOSWELL ROAD, LONDON, EC1M 7AD, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI<br>2012/1916)                       |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential  |
| <b>8: Authorisation Date</b>  | 29/06/2018  |
| <b>9: Annexes attached</b>  | 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

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