

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |  |
|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 51611   |
| <b>2: Name of authorisation holder</b>  | ROCIALLE HEALTHCARE LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, 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 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>  | 06/12/2023   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**ROCIALLE HEALTHCARE LIMITED**, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, UNITED KINGDOM

|   |
|---|
| Human Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.5 ] Packaging</b><br>[ 1.5.2 ] Secondary packaging |