

# 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> <b>[ 1.5 ] Packaging</b> [ 1.5.2 ] Secondary packaging