Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 51611
2: Name of authorisation holder	ROCIALLE HEALTHCARE LIMITED
3: Address(es) of manufacturing site(s)	ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, UNITED KINGDOM
4: Legally registered address of authorisation holder	ROCIALLE HEALTHCARE LIMITED, CWM CYNON BUSINESS PARK (NORTH), MOUNTAIN ASH, CF45 4ER, 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	04/09/2026
9: Annexes attached	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)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

MHRA-GMDP MHRA