Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 12845

2: Name of authorisation holder SPRINGDEW LIMITED

SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS

3: Address(es) of manufacturing site(s) PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, UNITED

KINGDOM

SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS

4: Legally registered address of authorisation holder PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, 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 12/07/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Issue Date: 12 Jul 2023