

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK ManA 32496

2: Name of authorisation holder AESICA QUEENBOROUGH LIMITED

3: Address(es) of manufacturing site(s) AESICA QUEENBOROUGH LIMITED, NORTH ROAD,
QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

4: Legally registered address of authorisation holder AESICA QUEENBOROUGH LIMITED, NORTH ROAD,
QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 5 of the current Veterinary Medicines Regulations

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 30/01/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AESICA QUEENBOROUGH LIMITED, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

Veterinary Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS 1. MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.13] Tablets [1.2.1.15] Intraruminal devices [1.2.1.17] Other non-sterile medicinal products Inhalation Anaesthetics [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.13] Tablets

[1.5.1.15] Intraruminal devices

[1.5.1.17] Other non-sterile medicinal products

INHALATION ANAESTHETICS

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical