

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 32496

2: Name of authorisation holder AESICA QUEENBOROUGH LIMITED

3: Address(es) of manufacturing site(s) AESICA QUEENBOROUGH LIMITED, BUILDING 55, 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 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 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, BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets Special Requirements Hormonal tablets [1.2.1.17] Other non-sterile medicinal products Inhalation Anaesthetics [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms [1.5.1.13] Tablets Special Requirements Hormonal tablets [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 Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.2] Microbiological: non-sterility [2.1.3] Chemical/Physical [2.2] Batch certification of imported medicinal products [2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing