

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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, BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
5: Scope of authorisation and dosage forms	AESICA QUEENBOROUGH LIMITED, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
6: Legal Basis of authorisation	ANNEX 1 and/ or ANNEX 2
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
8: Authorisation Date	Confidential
9: Annexes attached	30/01/2023
	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.13] Tablets Special Requirements Hormonal Tablets

[1.2.1.15] Other non-sterile medicinal products

Granules and Inhalation Anaesthetics

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.13] Tablets

Special Requirements

Hormonal Tablets

[1.5.1.15] Other non-sterile medicinal products

Granules and Inhalation Anaesthetics

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

AESICA QUEENBOROUGH LIMITED, BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.6] Liquids for internal use

[1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Nasal Inhalation Products, Oral inhalation Products

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Nasal Inhalation Products, Oral Inhalation Products