

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 32496
<b>2: Name of authorisation holder</b>	AESICA QUEENBOROUGH LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	AESICA QUEENBOROUGH LIMITED, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	AESICA QUEENBOROUGH LIMITED, BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	AESICA QUEENBOROUGH LIMITED, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
<b>6: Legal Basis of authorisation</b>	ANNEX 1 and/ or ANNEX 2
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>8: Authorisation Date</b>	Confidential
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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 <b>Special Requirements</b> 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