Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 32496 Version: 22

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1A

1. **Authorisation Number**

MIA(IMP) Number: MIA(IMP) 32496

2. **Name of Authorisation Holder**

AESICA QUEENBOROUGH LIMITED

3. **Trading Style**

4. **Address(es) of manufacturing/importing site(s)**
(All authorised sites should be listed if not covered by separate licences)

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
30433	AESICA QUEENBOROUGH LIMITED	NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
14900912	AESICA QUEENBOROUGH LIMITED	BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

5. **Legally registered address of Authorisation Holder**

NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM

6. **Scope of authorisation and dosage forms**

See Annex 2

7. **Legal basis of authorisation**

See Section 1B of authorisation.

8. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Olumuyiwa Abimbola

SECTION 1A (continued)

9. Date 25/02/2020

10. Annexes attached

Annex 2

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)

Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 32496 Version: 22

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] which implement Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001.

2. It permits the authorisation holder named on page 1 of Section 1 of the authorisation to manufacture, assemble and/or import investigational medicinal products for human use in accordance with Regulation 41 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] (as detailed in section 3 of this authorisation) and is subject to the provisions identified on page 2 of Section 1 of this authorisation.

3. In this document a Manufacturers Authorisation for Investigational Medicinal Products may be referred to as MIA(IMP) and the Medicines and Healthcare products Regulatory Agency (acting on behalf of the Licensing Authority as defined in Regulation 6 of The Human Medicines Regulations 2012 (SI 2012/1916) may be referred to as MHRA.

4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the manufacture, assembly or importation of investigational medicinal products.

Attention is drawn to the structure of this authorisation (as detailed on page 4 of Section 1) and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.

SECTION 1B (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

(a) Section 1 (this section) identifies the authorisation holder and the responsible officer for the issue of the authorisation. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.

(b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.

(c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.

(d) The authorisation holder is required to attach to his authorisation any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.

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6. Provisions

a) The provisions of Schedule 7 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] shall apply to the authorisation. For manufacture and/or assembly Parts 1 and 2 of Schedule 7 apply and for importation Parts 1 and 3 of Schedule 7 apply in accordance with Regulation 40(4) of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] subject to Regulation 38(2).

Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 32496 Version: 22

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
07/04/2011	Initial Application - Aesica Queenborough Limited
02/05/2013	Variation to add duns number to licence, Add Bretton Scot Smith as QP, Robert Davies as QC, Jarrett Palmer as PM and Richard Barnes-Austin as PM for site 30433. Remove Jeremy Tidmarsh as PM, Philip Lightowler as PM, Peter Casey as PM and QP, Anthony Allcock as PM and David Leaver as PM for site 30433
10/05/2013	Internal variation to remove Peter Casey and Anthony Allcock from site 30433
13/10/2014	Variation to site 30433 to add other non-sterile medicinal products - inhalation anaesthetics, remove Mr Richard Barnes-Austin, Mr Jarrett Palmer and John Budge as production manager, remove Mr M Worgan as QP and add Adam Burgess as QP, Christine Ernst as QC and Steve blackett, Roger Jones, Clifford Mann and richard Brenton as PM
06/02/2015	Variation: 1. Remove Mr P Smith & Mr D Gooding as QP's. 2. Add Dr B Rabiu as a new QP.
25/03/2015	Variation: Add Mr James Compton as Qualified Person
10/09/2015	Variation:1. Add Dr Faruk Ahmed as QP. 2. Remove Mr. Adam Burgess as a QP. 3. Add Mr Bryan Close as PM replacing Mr Roger Jones.
30/12/2015	Variation to site 30433 to: - add Mr Christopher David Howell (1258319) as QP - add Mrs Susan Cartwright (132194) as QP and QC - add Mrs Catherine Kay (443199) as QP - remove Mr Steve Blackett as PM - remove Mr Richard Brenton as PM - remove Dr Bodun Adbdulrahman Rabiu as QP - remove Mrs Christine Ernst as QC

04/04/2016	Variation: (SIte 30433) Add Mrs Sarah Mansfield as QC Add Mr Paul Gordon as QC Add Mr Dardan Reka as PM Add Mr Venkat Sunkara as Authorisation Holder, Communication, Invoicing and Site Contact Add Granules (Manufacture of Non-sterile) Remove Dr Faruk Ahmed as QP Remove Mrs Susan Cartwright as QP & QC Remove Mrs Sandra Lynn Castle as Authorisation Holder and Site Contact Additional: Remove Mr K Prescott as TQP Add Mr Alexander Crawford Humble as QP
03/06/2016	Variation: 1. Add Primary packaging of hard capsules (2.12.2). 2. Change invoice address to Aesica Queenborough Limited, North Road Queen Borough Kent MEI 1 5EL
05/09/2016	variation to: - add Paulina Postrach as a QP on site 30433 - add Intertek Pharmaceutical Services Manchester as a contract lab
28/11/2016	Variation: (Site 30433) Add Mr Tony Whelan as PM Add Mrs Catherine Claire Bateman as QP Add Ms Evangelia Asimakopoulou as QP Remove Mr James Compton as QP Remove Mr Bryan Close as PM Remove Mr Dardon Reka as PM Remove Paul Gordon as QC Remove Contract Laboratory(Hologic Limited) Amend communication and invoice contact to Mr Venkat Reddy Sunkara
05/05/2017	Variation: (Site 30433) Add Primary Packaging, Tablets Amend Communications and Invoicing Address to AESICA PHARMACEUTICALS LIMITED, ACCOUNTS PAYABLE, EQUINOX HOUSE, 3.2 SILVER FOX WAY, COBALT BUSINESS PARK, NEWCASTLE UPON TYNE, NE27 0QJ
20/02/2018	Variation to site 30433, AESICA QUEENBOROUGH LIMITED, NORTH ROAD QUEENBOROUGH, ME11 5EL UNITED KINGDOM for removal of: -Mr Clifford Mann 12097251 Production Manager -Mr Alexander Crawford Humble 135624 Qualified Person -Mrs Catherine Esther Kay 443199 Qualified Person --Ms Evangelia Asimakopoulou 16698885 Qualified Person --Mrs Sarah Louise Mansfield 15114057 Quality Controller --Mr Venkat Reddy Sunkara 15114333 Site Contact --Mr Tony Whelan 7267495 Production Manager --Mr Christopher David Howell 1258319 Qualified Person --Mr Robert Davies 9074482 Quality Controller Variation to add PM and QC to site 30433: -Production Manager Dr Aude Cazenave -Quality Controller Mr Mark Manser

10/05/2018	Variation: - add Waymade Plc (site 2814220) as a contract Lab - replace Mr Mark Manser with Dr Lee Rudge as QC on site 30433 - add Mr Justin Ahern (2044857) as a QP on site 30433
13/09/2018	Variation to site 30433: Remove Mr Bretton Smith and Mr Justin Valentine Ahern as QP's. Remove Dr Lee Rudge as a QC and add Dr Rod Henry and Mr Alexander Humble as QP's. Add Mr Paul Tucker as QC. - change communications and invoice address - change communications and invoice contact to Wendy Whitfield. Authorisation of the manufacture of liquids for external use.
29/11/2018	Variation to site: 30433 - Add Dr Ravindra Chambhare as QP - Add Dr Gary Reid as PM - Remove Miss Paulina Postrach QP - Remove Dr Aude Cazenave as PM
05/08/2019	Variation: - Remove Dr Gary Reid as PM - Add Mr Modestino Graziano as PM - Add site 14900912 - Add Transdermal patches
22/11/2019	Variation: - remove Mr Modestino Graziano as PM from site 30433 and site 14900912 - remove Dr Rodney Stephen Henry as QP from site 30433 and site 14900912 - add Dr David Jentsch as PM on site 30433 and site 14900912 - amend site address for Eurofins BPT UK Limited (replace site 89192 with site 17556174) - remove Mr Alexander Crawford Humble from site 30433 & site 14900912 - in section 1.2.1.15 amend from 'forn' to 'for' on site 14900912
21/01/2020	Variation (site 30433 & site 14900912): - remove Mrs Catherine Claire Bateman as QP - add Mr Siva Matam (19626777) as QP - add Mr Paul Wray (19577116) as QP
05/02/2020	Variation to add site 36790
25/02/2020	Internal variation to add Dr Wendy Whitfield as site contact for site 30433

Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 32496 MHRA Site No: 30433 VERSION: 22

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	AESICA QUEENBOROUGH LIMITED
ADDRESS:	NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
MHRA SITE NUMBER:	30433

Type of products handled

Human Investigational Medicinal Products for phase I, II, III clinical trials (optional)

Authorised operations

Manufacturing Operations of Investigational Medicinal Products (according to Part 1)	Authorised
Importation of Investigational Medicinal Products (according to Part 2)	Authorised

ANNEX 2 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	**Sterile Investigational Medicinal Products**	**Manufacture**
1.1.1	**Aseptically prepared (processing operations for the following dosage forms)**	
	1.1.1.1 Large volume liquids	Not Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Not Authorised
	1.1.1.4 Small volume liquids	Not Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised

1.1.2	***Terminally Sterilised (processing operations for the following dosage forms)***	**Manufacture**
	1.1.2.1 Large volume liquids	Not Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Not Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised
1.1.3	***Batch certification***	Not Authorised

1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	***Non-Sterile Products (processing operations for the following dosage forms)***	
	1.2.1.1 Capsules, hard shell	Not Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.3 Chewing gums	Not Authorised
	1.2.1.4 Impregnated matrices	Not Authorised
	1.2.1.5 Liquids for external use	Authorised
	1.2.1.6 Liquids for internal use	Not Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Not Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Not Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Authorised

	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products Granules and Inhalation Anaesthetics	Authorised
1.2.2	***Batch certification***	Not Authorised

1.3	**Biological investigational medicinal products**	**Manufacture**
1.3.1	***Biological medicinal products (list of product types)***	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	Not Authorised
	1.3.1.3 Cell therapy products	Not Authorised
	1.3.1.4 Gene therapy products	Not Authorised
	1.3.1.5 Biotechnology products	Not Authorised
	1.3.1.6 Human or animal extracted products	Not Authorised
	1.3.1.7 Tissue Engineered Products	Not Authorised
	1.3.1.8 Other biological medicinal products	Not Authorised
1.3.2	***Batch certification***	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	Not Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised

	1.3.2.5 Biotechnology products	Not Authorised
	1.3.2.6 Human or animal extracted products	Not Authorised
	1.3.2.7 Tissue Engineered Products	Not Authorised
	1.3.2.8 Other biological medicinal products	Not Authorised

1.4	***Other investigational medicinal products or manufacturing activity*** (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	**Manufacture**
1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
1.4.2	**Sterilisation of active substances/excipients/finished products:**	
	1.4.2.1 Filtration	Not Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Not Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	**Others**	Not Authorised

1.5	*Packaging*	Packaging
1.5.1	***Primary packing***	
	1.5.1.1 Capsules, hard shell	Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Not Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Not Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Authorised

	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	**Secondary packing**	Not Authorised

1.6	**Quality control testing**	
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Authorised
	1.6.3 Chemical/Physical	Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

ANNEX 2 – SITE INFORMATION (continued)

Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

2.1	**Quality control testing**	**Import**
	2.1.1 Microbiological: sterility	Not Authorised
	2.1.2 Microbiological: non-sterility	Not Authorised
	2.1.3 Chemical/Physical	Not Authorised
	2.1.4 Biological	Not Authorised
2.2	**Batch certification of imported medicinal products**	
2.2.1	***Sterile Products***	
	2.2.1.1 Aseptically prepared	Not Authorised
	2.2.1.2 Terminally sterilised	Not Authorised
2.2.2	***Non-sterile products***	Not Authorised
2.2.3	***Biological medicinal products***	
	2.2.3.1 Blood products	Not Authorised
	2.2.3.2 Immunological products	Not Authorised
	2.2.3.3 Cell therapy products	Not Authorised

	2.2.3.4 Gene therapy products	Not Authorised
	2.2.3.5 Biotechnology products	Not Authorised
	2.2.3.6 Human or animal extracted products	Not Authorised
	2.2.3.7 Tissue Engineered Products	Not Authorised
	2.2.3.8 Other biological medicinal products	Not Authorised
2.3	**Other Importation Activities**	
	2.3.1 Site of Physical Importation	Not Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Not Authorised
	2.3.3 Biological Active Substances	Not Authorised
	2.3.4 Other	Not Authorised

Any restrictions or clarifying remarks related to the scope of these importing operations:

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
19626777	Mr Sivanandaswamy Kalluholematam	Yes	No	No	No
19471525	Mr Paul Steven Tucker	No	No	No	Yes
20128046	Dr David Jentsch	No	No	Yes	No
19577116	Mr Paul Nigel Wray	Yes	No	No	No
3873386	Dr Ravindra Chambhare	Yes	No	No	No
17635767	Dr Wendy Whitfield	No	No	No	No

Key to Roles:

QP – Qualified Person
TQP – Transitional Qualified Person
PM – Production Manager/Supervisor
QC – Person responsible for Quality Control

Medicines & Healthcare products Regulatory Agency

MHRA

MIA(IMP) NUMBER: MIA(IMP) 32496 MHRA Site No: 14900912 VERSION: 22

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	AESICA QUEENBOROUGH LIMITED
ADDRESS:	BUILDING 55, NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
MHRA SITE NUMBER:	14900912

Type of products handled

Human Investigational Medicinal Products for phase I, II, III clinical trials (optional)

Authorised operations

Manufacturing Operations of Investigational Medicinal Products (according to Part 1)	Authorised
Importation of Investigational Medicinal Products (according to Part 2)	Not Authorised

ANNEX 2 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	**Sterile Investigational Medicinal Products**	**Manufacture**
1.1.1	**Aseptically prepared (processing operations for the following dosage forms)**	
	1.1.1.1 Large volume liquids	Not Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Not Authorised
	1.1.1.4 Small volume liquids	Not Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised

1.1.2	***Terminally Sterilised (processing operations for the following dosage forms)***	**Manufacture**
	1.1.2.1 Large volume liquids	Not Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Not Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised
1.1.3	***Batch certification***	Not Authorised

1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	***Non-Sterile Products (processing operations for the following dosage forms)***	
	1.2.1.1 Capsules, hard shell	Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.3 Chewing gums	Not Authorised
	1.2.1.4 Impregnated matrices	Not Authorised
	1.2.1.5 Liquids for external use	Authorised
	1.2.1.6 Liquids for internal use	Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Not Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Not Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Authorised

	1.2.1.14 Transdermal patches	Authorised
	1.2.1.15 Other non-sterile medicinal products Unidose forms for nasal delivery	Authorised
1.2.2	***Batch certification***	Not Authorised

1.3	**Biological investigational medicinal products**	**Manufacture**
1.3.1	***Biological medicinal products (list of product types)***	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	Not Authorised
	1.3.1.3 Cell therapy products	Not Authorised
	1.3.1.4 Gene therapy products	Not Authorised
	1.3.1.5 Biotechnology products	Not Authorised
	1.3.1.6 Human or animal extracted products	Not Authorised
	1.3.1.7 Tissue Engineered Products	Not Authorised
	1.3.1.8 Other biological medicinal products	Not Authorised
1.3.2	***Batch certification***	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	Not Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised

	1.3.2.5 Biotechnology products	Not Authorised
	1.3.2.6 Human or animal extracted products	Not Authorised
	1.3.2.7 Tissue Engineered Products	Not Authorised
	1.3.2.8 Other biological medicinal products	Not Authorised

1.4	***Other investigational medicinal products or manufacturing activity*** (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	**Manufacture**
1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
1.4.2	**Sterilisation of active substances/excipients/finished products:**	
	1.4.2.1 Filtration	Not Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Not Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	**Others**	Not Authorised

1.5	*Packaging*	Packaging
1.5.1	***Primary packing***	
	1.5.1.1 Capsules, hard shell	Not Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Not Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Not Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Not Authorised

	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	**Secondary packing**	Not Authorised

1.6	**Quality control testing**	
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Not Authorised
	1.6.3 Chemical/Physical	Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
3873386	Dr Ravindra Chambhare	Yes	No	No	No
19626777	Mr Sivanandaswamy Kalluholematam	Yes	No	No	No
17635767	Dr Wendy Whitfield	No	No	No	No
20128046	Dr David Jentsch	No	No	Yes	No
19471525	Mr Paul Steven Tucker	No	No	No	Yes
19577116	Mr Paul Nigel Wray	Yes	No	No	No
19577264	Mr Dave Bland	No	No	Yes	No

Key to Roles:

QP – Qualified Person
TQP – Transitional Qualified Person
PM – Production Manager/Supervisor
QC – Person responsible for Quality Control

ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
5712	BUTTERWORTH LABORATORIES LIMITED	54-56 WALDEGRAVE ROAD, TEDDINGTON, TW11 8NY, UNITED KINGDOM
38651	READING SCIENTIFIC SERVICES LIMITED	READING SCIENCE CENTRE, WHITEKNIGHTS CAMPUS, PEPPER LANE, READING, RG6 6LA, UNITED KINGDOM
343945	INTERTEK PHARMACEUTICAL SERVICES MANCHESTER	INTERTEK PHARMACEUTICAL SERVICES MANCHESTER, ANALYTICAL SERVICES GROUP, HEXAGON TOWER, CRUMPSALL VALE, BLACKLEY, MANCHESTER, M9 8GQ, UNITED KINGDOM
2814220	WAYMADE PLC	JOSSELIN ROAD, BURNT MILLS INDUSTRIAL ESTATE, BASILDON, SS13 1QF, UNITED KINGDOM
17556174	EUROFINS BIOPHARMA PRODUCT TESTING UK LIMITED	6-8 COCHRANE SQUARE, BRUCEFIELD INDUSTRY PARK, LIVINGSTON, EH54 9DR, UNITED KINGDOM

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
30433	AESICA QUEENBOROUGH LIMITED	NORTH ROAD, QUEENBOROUGH, ME11 5EL, UNITED KINGDOM
36790	AESICA PHARMACEUTICALS LIMITED	WINDMILL INDUSTRIAL ESTATE, SHOTTON LANE, CRAMLINGTON, NE23 3JL, UNITED KINGDOM