



Medicines & Healthcare products
Regulatory Agency

Ms Angela Rodda
ROCHE PRODUCTS LIMITED
6 FALCON WAY
SHIRE PARK
WELWYN GARDEN CITY
AL7 1TW
UNITED KINGDOM



MHRA
10 South Colonnade
Canary Wharf
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E14 4PU
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gov.uk/mhra



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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) 31

2. Name of Authorisation Holder

ROCHE PRODUCTS 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:
86087	ROCHE PRODUCTS LIMITED	6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM

5. Legally registered address of Authorisation Holder

6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM

6. Scope of authorisation and dosage forms

See Annex 2

7. Legal basis of authorisation

See Section 1B of authorisation.



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

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SECTION 1A (continued)

9. Date 28/10/2021

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)



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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use.
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).



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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
14/04/2004	Initial application
15/09/2006	Update current details of PM, add two QP's Mrs A Y Kingsland-Inwood and Miss A Hall.
20/07/2007	Variation to remove Mr David Garton from licence as he has left the company
28/09/2007	Variation to remove Dave Stevens as qualified person. To add Michael Breese & Barry Johnson as qualified persons.
08/11/2008	Update licence to EUDRA GMP format
24/11/2008	Update licence to EUDRA GMP format
12/01/2009	Variation to (1) Update site activities (Site 86087) (2) Add Contract Laboratory : RSSL
08/05/2009	Variation to site 86087: remove Mr M. Breese as QP and replace with Mr J Tognarelli, also amend site functions.
21/05/2009	Variation to site 86087: add Batch certification only to non-sterile products.
29/06/2010	Internal Variation
30/09/2010	Variation to replace Angela Rodda with Natasha Rowland as LHC., replace site 13053 with 86087., add Immunological products and remove Transdermal patches, Mrs A Y Kingsland-Inwood as QP from site 86087., add Catalent Packaging UK Limited and Aptuit as storage sites.
25/10/2010	Internal variation to correct errors
03/11/2010	Variation to replace Mrs Natasha Rowland with Ms Deb Mason as the Licence, Communications and Site Contact (86087)
04/01/2011	Variation to site 86087: add Miss S Aubert as QP.
14/02/2011	Variation to add site 28707 and 6963, change site 86087 and delete site 38651 and person 200740



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05/08/2011	Variation to add site 90874 for storage and handling.
25/07/2012	Variation: Add new site names on sites 29333 Catalent CTS (Edinburgh) Limited, Bathgate & 90874 Catalent CTS (Edinburgh) Limited, Deeside Unit 103.
23/11/2012	RBI - Variation to change name of site 29333 to CATALENT CTS (EDINBURGH) LIMITED
05/02/2013	Variation to amend company contact and site contact for site 86087 to Kevin Walsh, correct QP name of Alex Hall to the full name, delete J P Tognarelli as QP from site 86087
08/03/2013	Internal variation
08/03/2013	INTERNAL VARIATION REINSTATE MR J P TOGNARELLI.
17/06/2013	Variation:1. Remove Ms A Hall as QP/QC and replace with Miss S Aubert as QC.
09/09/2014	Variation to: 1) remove Mr Kevin Walsh (Person Number 6404532) as Company Contact and replace with Miss Angela Rodda. 2) add Ms Maria Adesida (person No. 3667479) is as an additional QP 3) add Mr John Tognarelli (Person Number 1806705) as QC 4) Deletion of Site 90874 and site 4858 as storage site
26/01/2015	Internal variation to replace Mr Kevin Walsh with Miss Angela Rodda (1554841)
26/01/2015	Internal variation to remove Miss Maria Adesida as QP
22/05/2015	Variation to add Mr Andrew Richards (1759369) as a QP on site 86087
02/10/2015	Variation: Remove Miss Silje Aubert as a QC & QP.
30/03/2016	Variation: Add Miss Helen O'Shea as an additional QP.
14/12/2016	Variation: (Site 86087) Remove Mr Andrew Norman Richards as QP Remove Storage & Handling site (Catalent UK Packaging Limited)
09/01/2019	Variation: - Add Miss Helen O'Shea as QC to site:86087 - Add storage Site: 10617701
26/06/2019	Variation: - Add Storage & Handling site: 18457585
20/09/2019	Variation to remove site 28707
03/02/2021	Variation to remove Miss Helen O'Shea and Add Mrs Claire Docksey as Qualified Person and Quality Control.
28/10/2021	Variation to add Other importation activities: Importation of QP certified IMPs from a country on the <input type="checkbox"/> approved country for import list <input type="checkbox"/> on site 86087



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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	ROCHE PRODUCTS LIMITED
ADDRESS:	6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM
MHRA SITE NUMBER:	86087

Type of products handled

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



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1.1.2	<i>Terminally Sterilised (processing operations for the following dosage forms)</i>	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	<i>Batch certification</i>	Authorised



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1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	<i>Non-Sterile Products (processing operations for the following dosage forms)</i>	
	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	Not 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	Not Authorised



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	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised
1.2.2	<i>Batch certification</i>	Authorised



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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	Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised



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



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1.4	<i>Other investigational medicinal products or manufacturing activity</i> (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 Batch Certification of non-sterile products/Importation of QP certified IMPs from a country on the <input type="checkbox"/> approved country for import list <input type="checkbox"/>	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



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1.4.3	Others	Not Authorised
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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



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	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



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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	Not 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	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	Non-sterile products	Authorised
2.2.3	Biological medicinal products	
	2.2.3.1 Blood products	Authorised
	2.2.3.2 Immunological products	Authorised
	2.2.3.3 Cell therapy products	Authorised



	2.2.3.4 Gene therapy products	Authorised
	2.2.3.5 Biotechnology products	Authorised
	2.2.3.6 Human or animal extracted products	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 Batch Certification of non-sterile products/Importation of QP certified IMPs from a country on the <input type="checkbox"/> approved country for import list <input type="checkbox"/>	Authorised

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



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ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>			
		<u>QP</u>	<u>TQP</u>	<u>PM</u>	<u>QC</u>
1806705	Mr J P Tognarelli	Yes	No	No	Yes
601578	Mrs Claire Docksey	Yes	No	No	Yes
1221698	Mr Barry Johnson	Yes	No	No	No
1554841	Ms Angela Rodda	No	No	No	No

Key to Roles:

QP – Qualified Person

TQP – Transitional Qualified Person

PM – Production Manager/Supervisor

QC – Person responsible for Quality Control



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ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
6963	ALLOGA UK LIMITED	AMBER PARK 1, 2, AND 3, BERRISTOW LANE, SOUTH NORMANTON, ALFRETON, DE55 2FH, UNITED KINGDOM
29333	CATALENT CTS (EDINBURGH) LIMITED	UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED KINGDOM
10617701	ALLOGA UK LIMITED	AMBER PARK 5 AND 6, UNIT C2, FARMWELL LANE, SOUTH NORMANTON, ALFRETON, DE55 2JX, UNITED KINGDOM
18457585	SHARP CLINICAL SERVICES (UK) LIMITED	UNIT 28, HEADS OF THE VALLEY INDUSTRIAL ESTATE, RHYMNEY, TREDEGAR, NP22 5RL, UNITED KINGDOM