



Mrs Susan Elizabeth Navarro
ISLESTONE LIMITED
UNIT 379A PRINCESWAY
TEAM VALLEY TRADING ESTATE
GATESHEAD
NE11 0TU
UNITED KINGDOM

MHRA

151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

[mhra.gov.uk](https://www.mhra.gov.uk)

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

Wholesale Distribution Authorisation (Human)

1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.
2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.
3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.
4. The authorisation is not transferable to another legal entity.
5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:
 - there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an “authorisation”) in force in relation to the product
 - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
 - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012 (SI 2012/1916).
6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission ‘Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products’ and future updates, in accordance with, The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]
7. If the intention is to import licensed medicinal products from outside the EEA an application for a manufacturer’s licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.

8. If the intention is to import a special medicinal product from outside the EEA into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.
9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.
10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.
11. The Medicines and Healthcare Products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).
12. Further information and specified guidelines may be obtained from the MHRA website (www.mhra.gov.uk).
13. Authorisation Structure

This Wholesale Distribution Authorisation is divided into five annexes.

- (a) Annex 1: Scope of wholesale distribution authorisation
- (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
- (c) Annex 3: Name(s) of responsible person(s.)
- (d) Annex 4: (Optional) Date of Inspection on which authorisation was granted
- (e) Annex 5: Additional provisions based on national requirements

Attention is drawn to the structure of this authorisation 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.

14. Authorisation Holder

(a) Authorisation Holder Number: WDA(H) 35640 has been granted to –

AUTHORISATION HOLDER:	ISLESTONE LIMITED
------------------------------	-------------------

TRADING AS:	
ADDRESS:	UNIT 379A PRINCESWAY, TEAM VALLEY TRADING ESTATE, GATESHEAD, NE11 0TU, UNITED KINGDOM
CONTACT NAME:	Mrs Susan Elizabeth Navarro

- (b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.
- (c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.
- (d) Date granted - 08/08/2014
- (e) Authorised by -

Name: Sean Kaiser

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 08/08/2014

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

Wholesale Distribution Authorisation (Human)

VARIATION HISTORY

Date	Variation Detail
21/10/2009	Initial Application.
21/10/2009	Internal variation to remove authorisation for Controlled Drugs.
17/11/2009	Variation to include the handling of Special manufactured products
28/01/2010	Variation to add Controlled Drugs to the licence.
07/12/2011	Variation to enable applicant to supply stock which requires refrigeration/low temperature storage and handle parallel imported medicinal products
29/10/2013	Variation to add site 8343031
09/05/2014	Variation to add procurement to site 8343031
19/06/2014	Internal Variation - to remove Hexham site ID 1087762.
08/08/2014	Internal Variation: Change LH address to reflect site address.

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

Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	ISLESTONE LIMITED
Address:	UNIT 379A PRINCESWAY, TEAM VALLEY TRADING ESTATE, GATESHEAD, NE11 0TU, UNITED KINGDOM
MHRA Site Number:	8343031

is named on Authorisation Holder number: WDA(H) 35640 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

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



Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA member state(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

- 3.1.1 Narcotic or psychotropic products

- 3.3 Cold chain products (requiring low temperature handling)

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	ISLESTONE LIMITED
Address:	UNIT 379A PRINCESWAY, TEAM VALLEY TRADING ESTATE, GATESHEAD, NE11 0TU, UNITED KINGDOM
MHRA Site Number:	8343031

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

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

Wholesale Distribution Authorisation (Human)

Annex 3 – Name(s) of designated Responsible Person(s)

Personnel

<u>Responsible Person</u>			
<u>Person Number</u>	<u>Name</u>	<u>Site</u>	<u>Role</u>
1987231	Mr Eric James Gulliford	8343031	Responsible Person