

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 16133

2: Name of authorisation holder ESSENTIAL NUTRITION LIMITED

3: Address(es) of manufacturing site(s) ESSENTIAL NUTRITION LIMITED, BANK HOUSE,
SALTGROUNDS ROAD, BROUGH, HU15 1EG, UNITED
KINGDOM

4: Legally registered address of authorisation holder ESSENTIAL NUTRITION LIMITED, BANK HOUSE,
SALTGROUNDS ROAD, BROUGH, HU15 1EG, UNITED
KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

**7: Name of responsible officer of the competent authority of the
member state granting the manufacturing authorisation** Confidential

8: Authorisation Date 14/10/2021

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ESSENTIAL NUTRITION LIMITED, BANK HOUSE, SALTGROUNDS ROAD, BROUGH, HU15 1EG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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 [1.2.1.3] Chewing gums [1.2.1.6] Liquids for internal use [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Semi Solid and dry extracts of funghi supercritical fluid extracts. Assembly of diagnostic kits

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Enzymes, Laccase, SOD, Cytochrome, P450, Proteases derived from funghi

[1.4] Other investigational medicinal products or manufacturing activities

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.4.1.2] Homeopathic products

[1.4.1.3] Other

Herbal & homeopathic products, vitamins, supplements and novel foodstuffs

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.8] Other biological medicinal products

Enzymes, Laccase, SOD, Cytochrome, P450, Proteases derived from funghi

[2.3] Other Importation Activities

[2.3.4] Other

Herbal & homeopathic products, vitamins, supplements and novel foodstuffs