

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK ManA 28255

**2: Name of authorisation holder** RUTLAND BIODYNAMICS LIMITED

**3: Address(es) of manufacturing site(s)** RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM,  
OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM,  
OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED  
KINGDOM

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

**6: Legal Basis of authorisation** Regulation 5 of the current Veterinary Medicines Regulations

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

**8: Authorisation Date** 08/09/2017

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**RUTLAND BIODYNAMICS LIMITED**, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM

Veterinary Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> 1. MANUFACTURING OPERATIONS <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile 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

[ 1.2.1.17 ] Other non-sterile medicinal products

Traditional Herbal products

[ 1.2.2 ] Batch certification

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.1 ] Herbal products

[ 1.4.1.3 ] Other

Hopguard, Liquid topical ectoparasitic for bees (minor use, minor species)

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.5 ] Liquids for external use

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**2. IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical