



## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### Non-UK Manufacturer

#### Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended.

The competent authority of: UNITED KINGDOM (**Veterinary**) confirms the following:

The manufacturer: **Mars Fishcare Inc**

Site address: 50 East Hamilton Street  
PO Box 218  
Chalfont  
Pennsylvania 18914  
United States of America

Has been inspected in connection with products marketed under Schedule 6 listing manufacturers located outside of the European Economic Area in accordance with Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:

#### The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **24<sup>th</sup> & 25<sup>th</sup> September 2019**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 23 October 2019

Name: CONFIDENTIAL

## Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: Not applicable
1.2	Non-sterile products: 1.2.1.5 Liquids for external use
1.3	Biological medicinal products: Not applicable
1.4	Other products or manufacturing activity: Not applicable
1.5	Packaging: 1.5.1.5 Primary packing of liquids for external use 1.5.2 Secondary packing
1.6	Quality Control testing:  1.6.3 Chemical/Physical

**Any restrictions or clarifying remarks related to the scope of this certificate:**

**Schedule 6 (Exemption for Small Pet Animals) Non-sterile only products for use in fish ponds and aquariums where the administration route is via water.**

**The active substances permitted for use in manufacture are as per the list of approved substances published on the VMD's pages accessed via the gov.uk website.**

Name and signature of the authorised person of  
the Competent Authority of the UK:

CONFIDENTIAL

Signature: \_\_\_\_\_

Date: 23 October 2019

Name:

CONFIDENTIAL

Veterinary Medicines Directorate  
tel: +CONFIDENTIAL  
email CONFIDENTIAL