

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 30812 Insp GMP 30812/336305-0004

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

### Part 1

Issued following an inspection in accordance with :

Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : CRODA EUROPE LIMITED

Site address : CRODA EUROPE LIMITED, BARNFIELD ROAD, LEEK, ST13 5QJ, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27/01/2025 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.
  - (2) These requirements fulfil the GMP recommendations of WHO.

### Part 2

#### Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [4000016939] FISH OIL, RICH IN OMEGA-3 ACIDS
- [2000006881] OMEGA-3-ACID ETHYL ESTERS 90
- [2000006478] OMEGA-3-ACID TRIGLYCERIDES

#### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

FISH OIL, RICH IN OMEGA-3 ACIDS

3.2 Processing Activities of Active Substance from Natural Sources

### 3.2.2 Animal Source Extraction

### 3.2.6 Purification of extracted substance

## 3.5 General Finishing Steps

### 3.5.1 Physical Processing Steps

Distillation, Clay Bleaching, Carbon Treatment, Filtration

### 3.5.2 Primary Packaging

## 3.6 Quality Control Testing

### 3.6.1 Physical / Chemical testing

### 3.6.2 Microbiological testing (excluding sterility testing)

### 3.6.4 Biological Testing

## OMEGA-3-ACID ETHYL ESTERS 90

### 3.1 Manufacture of Active Substance by Chemical Synthesis

#### 3.1.1 Manufacture Of Active Substance Intermediates

#### 3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Manufacture of omega-3 ethyl esters is a series of purification steps from Crude or Semi-Refined marine oil

## 3.5 General Finishing Steps

### 3.5.1 Physical Processing Steps

esterification, distillation, clathration, clay bleaching, carbon treatment, filtration

### 3.5.2 Primary Packaging

## 3.6 Quality Control Testing

### 3.6.1 Physical / Chemical testing

### 3.6.2 Microbiological testing (excluding sterility testing)

## OMEGA-3-ACID TRIGLYCERIDES

### 3.1 Manufacture of Active Substance by Chemical Synthesis

#### 3.1.1 Manufacture Of Active Substance Intermediates

#### 3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Manufacture of omega-3-acid triglycerides is a series of purification steps from Crude or Semi-Refined Marine Oil

## 3.5 General Finishing Steps

### 3.5.1 Physical Processing Steps

esterification, distillation, clathration, glycerolysis, clay bleaching, carbon treatment, filtration

### 3.5.2 Primary Packaging

**Restrictions or Remarks**

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

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| 27/01/2025 | Name and signature of the authorised person of the Competent Authority of United Kingdom<br>Confidential<br>Medicines and Healthcare products Regulatory Agency<br>Tel : Confidential |
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