Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 30812 Insp GMP 5114/16026-0002

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, FOUNDRY LANE, DITTON, WIDNES, WA8 8UB, UNITED KINGDOM
Other :
Requested by US FDA under Article 11 of USA-EU MRA.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/10/2024, 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.

- *(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 :

- [1000009323] TITANIUM DIOXIDE
- [2000008399] ZINC OXIDE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

TITANIUM DIOXIDE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.4 Mineral Source Extraction

	3.2.5 Modification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Bead milling and dispersion in oil or water
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

ZINC OXIDE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.4 Mineral Source Extraction
	3.2.5 Modification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Bead milling and dispersion in oil or water
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

Restrictions or Remarks

The GMP certificate applies to the manufacture, packaging and testing of metal oxides only. Other manufacturing activities on site are excluded.

14/05/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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