Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 2021 Insp GMP 2021/13222-0011

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 : FUCHS LUBRICANTS (UK) PLC

Site address : FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, 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 19/12/2024 , 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 :

- [2000008090] PARAFFIN LIGHT LIQUID
- [2000008087] PARAFFIN SOFT YELLOW
- [2000008089] PARAFFIN LIQUID
- [2000008088] PARAFFIN SOFT WHITE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

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PARAFFIN LIGHT LIQUID

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.4 Mineral Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps 5 micron or better filtration.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

PARAFFIN SOFT YELLOW

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.4 Mineral Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Mixing of waxes and oils. Better than 5 micron filtration. Vacuum steam stripping and Fullers Earth treatment followed by high vacuum steam deodorisation.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

PARAFFIN LIQUID

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.4 Mineral Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps 5 micron or better filtration.
	3.5.2 Primary Packaging

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	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

PARAFFIN SOFT WHITE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.4 Mineral Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps 5 micron or better filtration. Vacuum steam stripping, Fullers Earth treatment and high vacuum steam deodorisation.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

19/12/2024	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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