# Medicines and Healthcare products Regulatory Agency

## CERTIFICATE NUMBER : UK API 11718 Insp GMP 11718/56821-0001

## 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 : R MASON CHEMICALS LIMITED

Site address : R MASON CHEMICALS LIMITED, HARELAW INDUSTRIAL ESTATE, STANLEY, DH9 8UL, UNITED KINGDOM
Other :
API manufacturer (not required API registration in UK)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 02/02/2022, 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 :

- [3000010141] SELENIUM SULFIDE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

SELENIUM SULFIDE

| | |
|---|---|
| 3.1 | Manufacture of Active Substance by Chemical Synthesis |
| | 3.1.4 Other |
| | Non-sterile Active Pharmaceutical Ingredient by fusion |

| | |
|---|---|
| 3.5 | General Finishing Steps |
| | 3.5.1 Physical Processing Steps<br>Fusion, Annealing, Milling, Micronisation |
| | 3.5.2 Primary Packaging |
| 3.6 | Quality Control Testing |
| | 3.6.1 Physical / Chemical testing |

**Restrictions or Remarks**

Active substance manufacturer for export to MRA country (USA), in which the active substance was used in manufacturing of a topical human drug product.

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| 25/03/2022 | 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 |