Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 53819 Insp GMP 53819/14921-0011[H]

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 : KDC\ONE SWALLOWFIELD LIMITED

Site address : KDC\ONE SWALLOWFIELD LIMITED, SWALLOWFIELD HOUSE, STATION ROAD, WELLINGTON, TA21 8NL, UNITED KINGDOM
Other :
Good Manufacturing Practice: Anti-perspirant manufacturer for export to MRA countries, in which anti-perspirants are classified as medicines.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 13/04/2021, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.11] Semi-solids

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
	This GMP certificate is restricted to the manufacture of anti-perspirant sticks in Manufacturing Room 5 and Filling Line 4 for markets where they are classified as medicinal products.			

17/03/2022 Name and signature of the authorised person of the Competent Authority of United Kingdom
Confidential
Medicines and Healthcare products Regulatory Agency
Tel : Confidential