Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 10866 Insp GMP 10866/1722-0015

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 : NICOBRAND LIMITED

Site address : NICOBRAND LIMITED, UNIT 1, 189 CASTLEROE ROAD, COLERAINE, BT51 3RP, 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 01/06/2021 , 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 :

- [2000006474] NICOTINE POLACRILEX
- [1000009685] NICOTINE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

NICOTINE POLACRILEX

3.1 Manufacture of Active Substance by Chemical Synthesis

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	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Fixing Nicotine to an ion excahnge resin
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps ion exchange resin bonding, drying and milling
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

NICOTINE

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.1 Plant Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Distillation
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

21/02/2024	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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