Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 24 Insp GMP 24/18490046-0004

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 : COURTIN & WARNER LIMITED

Site address : COURTIN & WARNER LIMITED, UNIT F, MALLING BROOKS, BROOKS ROAD, LEWES, BN7 2QG, 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 01/10/2025 , 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 :

- [4000007414] PHENOBARBITONE SODIUM
- [1000002667] ETHAMBUTOL
- [1000009661] NYSTATIN
- [1000007380] GABAPENTIN
- [1000008543] LORAZEPAM
- [2000008271] CAFFEINE CITRATE

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- [1000009411] SUCRALFATE
- [1000001509] CAFFEINE AND SODIUM BENZOATE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

PHENOBARBITONE SODIUM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other
	Repacker
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Re-packer
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

ETHAMBUTOL

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other
	Re-packer
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Repacking
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

NYSTATIN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other
	Re-packer
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Re-packer
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

GABAPENTIN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other
	Re-packer
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Re-packer

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	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

LORAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other Re-packer
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Repacker
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

CAFFEINE CITRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
3.5	General Finishing Steps
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

SUCRALFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other Re-packer
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Repacker
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

CAFFEINE AND SODIUM BENZOATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates

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	3.1.2 Manufacture Of Crude Active Substance
3.5	General Finishing Steps
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Restrictions or Remarks

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

02/01/2026	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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