Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 2000 Insp GMP 2000/12918-0013

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of United Kingdom confirms the following :

The Manufacturer : NORBROOK LABORATORIES LIMITED

Site address : NORBROOK LABORATORIES LIMITED, STATION WORKS, CAMLOUGH ROAD, NEWRY, BT35 6JP, 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 22/09/2014 , 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

Veterinary Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [4000013029] CLOXACILLIN BENZATHINE WITH 1% LECITHIN
- [2000015744] CLOXACILLIN BENZATHINE
- [2000007766] DIHYDROSTREPTOMYCIN SULPHATE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

CLOXACILLIN BENZATHINE WITH 1% LECITHIN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	B-lactam Antibiotics
	3.1.2 Manufacture Of Crude Active Substance
	B-lactam Antibiotics
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) crystallisation
	B-lactam Antibiotics
3.4	Manufacture of sterile active substance
	3.4.2 Terminally sterilised
	Other : Gamma irradiated under contract
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	B-lactam Antibiotics

CLOXACILLIN BENZATHINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	B-lactam Antibiotics
	3.1.2 Manufacture Of Crude Active Substance
	B-lactam Antibiotics
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) crystallisation
	B-lactam Antibiotics
3.4	Manufacture of sterile active substance
	3.4.2 Terminally sterilised
	Other : Gamma irradiated under contract
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	B-lactam Antibiotics

DIHYDROSTREPTOMYCIN SULPHATE

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
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) RO/UF concentration - API is a liquid
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
	3.6.2 Microbiological testing (excluding sterility testing)

20/11/2014	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential