Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 43175 Insp GMP 43175/9985247-0001 [V]

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 : ANIDRO DO BRASIL EXTRACOES SA

Site address : ANIDRO DO BRASIL EXTRACOES SA, RUA POLICARPINA, 1000 BAIRRO IGARACU, PARNAIBA, PIAUI, BR-64216 815, BRAZIL

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with API-A80(1)-D2001/82/EC Regulation 5 of The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/03/2014, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations

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 :

- [2000008003] PILOCARPINE NITRATE
- [2000008004] PILOCARPINE HYDROCHLORIDE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

PILOCARPINE NITRATE

3.2 Processing Activities of Active Substance from Natural Sources

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	3.2.1 Plant Source Extraction
	3.2.6 Purification of extracted substance
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Sieving
	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)

PILOCARPINE HYDROCHLORIDE

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 Sieving
	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)

22/10/2014	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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