Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: *NL/H 17/1015376V1*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Laboratorium Ofichem B.V.***
Site address: ***Heembadweg 5, TER APEL, 9561CZ, Netherlands***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-05-02*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

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 EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection :
CISPLATIN(en)
CARBOPLATIN(en)
PAMIDRONIC ACID(en)
DISODIUM PAMIDRONATE(en)
DIMETHYLFUMARATE(en)
SULFADIAZINE SODIUM(en)
SULFADIMIDINE SODIUM(en)
SULFATHIAZOLE SODIUM(en)
SULFADIMETHOXINE SODIUM(en)
SULFAMETHOXYPYRIDAZINE SODIUM(en)
SULFACHLOROPYRIDAZINE SODIUM(en)
LEVAMISOLE(en)
AMMONIUM SULFATE(en)
CIS-OXOPLATIN(en)
COLLISTINE SULFATE(en)
CYAMEMAZINE(en)
DIETHYLFUMARATE(en)
DISODIUM ALENDRONATE(en)
DISODIUM ETIDRONATE(en)
CYCLOBUTANE DICARBOXYLIC ACID(en)
DISODIUM PAMIDRONATE PENTAHYDRATE(en)
ETHYL HYDROGENFUMARATE CALCIUM(en)
ETHYL HYDROGENFUMARATE MAGNESIUM(en)
ETHYL HYDROGENFUMARATE ZINC(en)
ETIDRONIC ACID(en)
ETOPOSIDE(en)
FORMIC ACID(en)
HISTAMINE DIHYDROCHLORIDE(en)
HISTAMINE PHOSPHATE(en)
IMIDAZOLE ACETIC ACID(en)
ISOTHIPENDYL(en)
POTASSIUM HEXACHLOROPATINATE(en)
POTASSIUM OXONIC ACID(en)
LEVAMISOLE PHOSPHATE(en)
METHENAMINE HIPPURATE(en)
METHENAMINE MANDELATE(en)
MONOETHYL FUMARIC ACID(en)
MONOMETHYLFUMARATE(en)
OLPADRONATE DISODIUM(en)
OLPADRONIC ACID(en)
OXALIC ACID(en)
OXALIPLATIN(en)
PIPERAZINE CITRATE(en)
PHTHALYLSULFATHIAZOLE(en)
RHODAVET(en)

SILVER NITRATE(en)
SODIUM ALENDRONATE(en)
SULFAMERAZINE SODIUM MONOHYDRATE(en)
SULFANILAMIDE SODIUM(en)
SULFAQUINOXALINE SODIUM(en)
TETRACHLOROPLATINATE(en)
THIAZINAMIUM METHYLSULFATE(en)
TRANS PT(DACH)CL2(en)
TRANS-(R,R)-1,2-DIAMINOCYCLOHEXANE(en)
ZINC ACETATE(en)
ZOLEDRONIC ACID(en)

Clarifying remarks (for public users)

Following a risk-based review of GMP compliance information conducted on 4 April 2020, the validity period of this certificate is extended to 2 May 2021.

2020-04-04

Name and signature of the authorised person of the Competent Authority of Netherlands

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Confidential
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel: ***Confidential***
Fax ***Confidential***