Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 8913 Insp GMP 8913/18322-0006

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 : WOCKHARDT LIMITED

Site address : WOCKHARDT LIMITED, L-1, MIDC, JALGAON ROAD, CHIKALTHANA, AURANGABAD, IN-431 210, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 17 Part 16 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 11/11/2013, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 :

- [4000006734] OXYBUTYNIN CHLORIDE
- [2000016830] CHLOROTHIAZIDE SODIUM
- [1000009945] EPINEPHRINE
- [2000010996] BETHANECHOL CHLORIDE
- [4000011693] PRAMIPEXOLE DIHYDROCHLORIDE
- [4000013915] WCK 771
- [1000002661] NADIFLOXACIN

- [2000016831] GATIFLOXACIN HEMIHYDRATE
- [1000003230] ZONISAMIDE
- [1000006787] CAPTOPRIL
- [2000016014] FESOTERODINE FUMARATE
- [2000018014] EPINEPHRINE BITARTRATE
- [2000015746] SAXAGLIPTIN HYDROCHLORIDE
- [3000017469] ZOLPIDEM BASE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

OXYBUTYNIN CHLORIDE

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying and 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)

CHLOROTHIAZIDE SODIUM

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling and 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)

EPINEPHRINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying and 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)

BETHANECHOL CHLORIDE

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling and seiving
	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)

PRAMIPEXOLE DIHYDROCHLORIDE

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling and 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)

WCK 771

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling and 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)

NADIFLOXACIN

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) Crystallisation
3.5	General Finishing Steps

	3.5.1 Physical Processing Steps Drying and sieving
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

GATIFLOXACIN HEMIHYDRATE

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying and 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)

ZONISAMIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling, seiving and blending
	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)

CAPTOPRIL

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling, sieving and blending
	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)

FESOTERODINE FUMARATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, milling and sieving
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

EPINEPHRINE BITARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying and 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)

SAXAGLIPTIN HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying and sieving
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ZOLPIDEM BASE

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

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products

This inspection covered the API manufacturing facilitiies only in L1 Chikalthna in process houses PH I, II, IV V and VI

16/04/2014	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential