Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 34460 Insp GMP 34460/720129-0005 [H]

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 : YONSUNG FINE CHEMICALS COMPANY LIMITED

Site address : YONSUNG FINE CHEMICALS COMPANY LIMITED, 207 SUJEONG-RO, JANGAN-MYEON, HWASEONG-SI, GYEONGGI-DO, KR-18581, SOUTH KOREA

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 26/11/2012, 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 :

- [1000003182] ALPROSTADIL
- [2000007625] CISATRACURIUM BESYLATE
- [2000007668] EPOPROSTENOL SODIUM
- [1000009076] MISOPROSTOL
- [2000009151] TREPROSTINIL SODIUM
- [4000013362] PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE

- [2000008448] ATRACURIUM BESYLATE
- [2000007876] TAMSULOSIN HYDROCHLORIDE
- [4000012823] MISOPROSTOL HPMC 1% DISPERSION
- [1000003257] LATANOPROST
- [1000016469] LIMAPROST
- [1000000645] BIMATOPROST
- [1000007990] BROMFENAC
- [1000000660] TRAVOPROST
- [2000007274] IMIDAPRIL HYDROCHLORIDE
- [2000014372] BERAPROST SODIUM
- [1000007347] CABERGOLINE
- [2000007863] LEVOCABASTINE HYDROCHLORIDE
- [1000003754] ILOPROST

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

ALPROSTADIL

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

CISATRACURIUM BESYLATE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

EPOPROSTENOL 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
3.5	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
	3.6.2 Microbiological testing (excluding sterility testing)

MISOPROSTOL

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

TREPROSTINIL 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
3.5	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
	3.6.2 Microbiological testing (excluding sterility testing)

PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

ATRACURIUM BESYLATE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

TAMSULOSIN HYDROCHLORIDE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

MISOPROSTOL HPMC 1% DISPERSION

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
	3.5.1 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

	3.6.2 Microbiological testing (excluding sterility testing)

LATANOPROST

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

LIMAPROST

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

BIMATOPROST

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

BROMFENAC

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

TRAVOPROST

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

IMIDAPRIL HYDROCHLORIDE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

BERAPROST 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
3.5	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
	3.6.2 Microbiological testing (excluding sterility testing)

CABERGOLINE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

LEVOCABASTINE HYDROCHLORIDE

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

ILOPROST

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
	3.5.1 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
	3.6.2 Microbiological testing (excluding sterility testing)

Restrictions or Remarks

GMP Certificate re-issued due to change of allocated address of the site- no further inspection conducted.

17/02/2014	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential