Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 34460 Insp GMP 34460/720129-0004

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
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 26/11/2012, it is considered that it complies with:

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

MHRA-GMDP MHRA

- [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

MHRA-GMDP MHRA-GMDP MHRA MHRA

	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

MHRA-GMDP

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

MHRA-GMDP MHRA-GMDP MHRA MHRA-GMDP MHRA-GMDP MHRA

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

MHRA-GMDP MHRA-GMDP MHRA MHRA-GMDP MHRA

	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

MHRA-GMDP

	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

MHRA-GMDP MHRA-GMDP MHRA MHRA

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

MHRA-GMDP MHRA-GMDP MHRA MHRA

	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

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3.6.2 Microbiological testing (excluding sterility testing)

14/02/2013	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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