Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 15298 Insp GMP 15298/358411-0001

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 : DIVI'S LABORATORIES LIMITED

Site address : DIVI'S LABORATORIES LIMITED, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, IN-508 252, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 17 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 13/12/2016, 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 :

- [1000007832] IOPAMIDOL
- [1000007298] ATOVAQUONE
- [1000000735] DESLORATADINE
- [2000007835] DEXTROMETHORPHAN HYDROBROMIDE
- [1000003241] DEXTROMETHORPHAN
- [1000013222] LEVETIRACETAM

- [1000000402] NABUMETONE
- [1000009701] NAPROXEN
- [2000008310] PROGUANIL HYDROCHLORIDE
- [2000005649] QUETIAPINE FUMARATE
- [1000008495] TELMISARTAN
- [1000009498] LAMOTRIGINE
- [2000007961] VALACICLOVIR HYDROCHLORIDE
- [2000008037] ZOLPIDEM TARTRATE
- [1000009387] SULPHASALAZINE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

IOPAMIDOL

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying and sieving are carried out in-house at Divis Laborato
	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)

ATOVAQUONE

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) Precipitation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying and micronisation are carried out in-house at Divis La
	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)

DESLORATADINE

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, milling, sieving and micronisation is carried out in-
	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)

DEXTROMETHORPHAN HYDROBROMIDE

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, milling, micronisation & sieving are carried out in-ho
	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)

DEXTROMETHORPHAN

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying and sieving are carried out in-house at Divis Laborato
	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)

LEVETIRACETAM

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, milling, micronisation, sieving are carried out in-hou
	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)

NABUMETONE

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing i.e like drying, micronisation, sieving are carried out in-house at Divi
	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)

NAPROXEN

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) Precipitation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, milling, micronisation, sieving are carried out in-hou
	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)

PROGUANIL 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

	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, milling, micronisation & sieving are carried out in-ho
	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)

QUETIAPINE FUMARATE

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) Crystallization
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps All the physical processing steps i.e drying, micronisation & sieving are carried out in-house at Di
	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)

TELMISARTAN

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) Precipitation
3.5	General Finishing Steps

3.5.1 Physical Processing Steps

All the physical processing steps i.e drying, milling, micronisation, sieving are carried out in-hou

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)

LAMOTRIGINE

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)

Precipitation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

All the physical processing steps i.e drying is carried out in-house at Divis Laboratories Limited.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

VALACICLOVIR 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

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Crystallization

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

All the physical processing steps i.e drying, milling & sieving are carried out in-house at Divis L

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)

ZOLPIDEM TARTRATE

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)
Crystallization

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
All the physical processing steps i.e drying & sieving are carried out in-house at Divis Laboratori

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)

SULPHASALAZINE

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)
crystallization

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
All the physical processing steps i.e drying & sieving are carried out in-house at Divis Laboratori

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
				Inspection also covered manufacture of the following intermediates: FAPE, R-Amine, Sulphazine, Thiol Acid. The reference to Lamotrigine on the GMP certificate refers to intermediate only.

15/02/2017	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential