OGYÉI National Institute of Pharmacy and Nutrition

H-1051 Budapest, Zrinyi utca 3.
1372 P.O. Box 450
Tel.: +36 1 886 9300, Fax: +36 1 886 9460
E-mail: ogyei@ogyei.gov.hu
Web: www.ogyei.gov.hu

National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER : ***OGYÉI/38694-8/2021***

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 Hungary confirms the following:
The manufacturer :***Teva Gyógyszergyár Zártkörűen Működő Részvénytársaság (Teva Gyógyszergyár Zrt.)/Teva Pharmaceutical Works Private Limited Company (Teva Pharmaceuticals Ltd.)***
Site address :***Pallagi út 13., Debrecen, 4042, Hungary***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-06-29*** , 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.

[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 :
BICALUTAMIDE(en)
TOBRAMYCIN(en)
PRAVASTATIN SODIUM(en)
SIMVASTATIN(en)
MUPIROCIN CALCIUM(en)
MUPIROCIN(en)
IMIQUIMOD(en)
ONDANSETRON BASE(en)
ONDANSETRON HYDROCHLORIDE DIHYDRATE(en)
DEFEROXAMINE MESYLATE(en)
LOVASTATIN(en)
MYCOPHENOLATE SODIUM(en)
CYCLOSPORINE(en)
ZALEPLON(en)
LEVODOPA(en)
TACROLIMUS(en)
CASPOFUNGIN INTERMEDIATE (PB0-BUTO-AM)(en)
ANIDULAFUNGIN INTERMEDIATE(en)
MICAFUNGIN INTERMEDIATE(en)
MYCOPHENOLIC ACID(en)
MIDOSTAURIN(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance :BICALUTAMIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance :TOBRAMYCIN	
3.3	**Manufacturing of Active Substance using Biological Processes**

	3.3.1 Fermentation 3.3.3 Isolation / Purification 3.3.4 Modification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :PRAVASTATIN SODIUM

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :SIMVASTATIN

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: .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for

	identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :MUPIROCIN CALCIUM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :MUPIROCIN

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :IMIQUIMOD

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: .

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :ONDANSETRON BASE

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: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :ONDANSETRON HYDROCHLORIDE DIHYDRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :DEFEROXAMINE MESYLATE	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance :LOVASTATIN	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification 3.3.4 Modification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance :MYCOPHENOLATE SODIUM	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :CYCLOSPORINE

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :ZALEPLON

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: .
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance :LEVODOPA

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

	3.6.2 Microbiological testing excluding sterility testing
Active Substance :TACROLIMUS	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance :CASPOFUNGIN INTERMEDIATE (PB0-BUTO-AM)	
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: .
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance :ANIDULAFUNGIN INTERMEDIATE	
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: .
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MICAFUNGIN INTERMEDIATE

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: .
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MYCOPHENOLIC ACID

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance :MIDOSTAURIN

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation 3.3.3 Isolation / Purification 3.3.4 Modification
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

2021-08-06

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

Dr. Ferenc Lukacs
National Institute of Pharmacy and Nutrition
Tel:*+36 1 8869300*
Fax:*+36 1 8869463*