Health Products Regulatory Authority

CERTIFICATE NUMBER: 2019/25698 2

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Ireland confirms the following:

The manufacturer: Divi's Laboratories Limited

Site address: Unit – 2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, 531 162, India

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

Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-08-30**, 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.

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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:

LEVODOPA(en)

ORLISTAT(en)

ISAVUCONAZOLE(en)

LEVETIRACETAM(en)

RITONAVIR(en)

ABACAVIR(en)

LETERMOVIR(en)

RALTEGRAVIR POTASSIUM(en)

SITAGLIPTIN PHOSPHATE(en)

BOSENTAN MONOHYDRATE(en)

DORAVIRINE(en)

CARBIDOPA MONOHYDRATE(en)

VIGABATRIN(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: LEVODOPA

Active Substance . LE vobol A		
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 :	
	Crystallization	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Milling, sieving, micronization and blending	
	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	
	2.6.1 Dhysical / Chamical testing	

3.6.1 Physical / Chemical testing

Active Substance: ORLISTAT

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 :	
	Crystallisation	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Micronisation	

Issuance Date: 2020-01-30

3.5.2 Primary Packaging (enclo			
	sing / 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 packag			
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 testin	ng		
Active Substance : ISAVUCONAZOLE			
3.1 Manufacture of Active Substar	.1 Manufacture of Active Substance by Chemical Synthesis		
3.1.1 Manufacture of active sul	ostance intermediates		
3.5 General Finishing Steps			
3.5.1 Physical processing steps Filtration Drying			
, ,	sing / sealing the active substance within a packaging material		
which is in direct contact with th			
3.5.3 Secondary Packaging (pla	acing the sealed primary package within an outer packaging		
	ncludes any labelling of the material which could be used for		
	numbering) of the active substance)		
3.6 Quality Control Testing			
3.6.1 Physical / Chemical testin	ng		
Active Substance : LEVETIRACETAM			
3.1 Manufacture of Active Substar			
3.1.1 Manufacture of active sul	ostance intermediates		
3.5 General Finishing Steps			
3.5.1 Physical processing steps	:		
Drying			
Drying 3.5.2 Primary Packaging (enclo	osing / sealing the active substance within a packaging material		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the	using / sealing the active substance within a packaging material e substance)		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the secondary Packaging (place).	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (plamaterial or container. This also in	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the solution of the solu	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (plamaterial or container. This also in identification or traceability (lot a 3.6 Quality Control Testing	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance)		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the solution of the solu	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance)		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (plamaterial or container. This also in identification or traceability (lot a 3.6 Quality Control Testing	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance)		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (plamaterial or container. This also in identification or traceability (lot a 3.6 Quality Control Testing 3.6.1 Physical / Chemical testing	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance)		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (playmaterial or container. This also in identification or traceability (lot in identification) 3.6 Quality Control Testing 3.6.1 Physical / Chemical testine Active Substance: RITONAVIR	osing / sealing the active substance within a packaging material e substance) nacing the sealed primary package within an outer packaging neludes any labelling of the material which could be used for numbering) of the active substance) age age ace by Chemical Synthesis		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (playmaterial or container. This also in identification or traceability (lot is 3.6 Quality Control Testing 3.6.1 Physical / Chemical testine Active Substance: RITONAVIR 3.1 Manufacture of Active Substance	osing / sealing the active substance within a packaging material e substance) nacing the sealed primary package within an outer packaging neludes any labelling of the material which could be used for numbering) of the active substance) age age ace by Chemical Synthesis		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (plamaterial or container. This also in identification or traceability (lot 3.6 Quality Control Testing 3.6.1 Physical / Chemical testin Active Substance: RITONAVIR 3.1 Manufacture of Active Substance 3.1.1 Manufacture of active substance substa	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance) age ace by Chemical Synthesis ostance intermediates		
Drying 3.5.2 Primary Packaging (enclowhich is in direct contact with the 3.5.3 Secondary Packaging (planaterial or container. This also in identification or traceability (lot 3.6 Quality Control Testing 3.6.1 Physical / Chemical testine Active Substance: RITONAVIR 3.1 Manufacture of Active Substance 3.1.1 Manufacture of active substance 3.5.1 Physical processing steps Drying Milling	osing / sealing the active substance within a packaging material e substance) acing the sealed primary package within an outer packaging acludes any labelling of the material which could be used for numbering) of the active substance) age ace by Chemical Synthesis ostance intermediates		

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	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			
Activ	Active Substance : ABACAVIR			
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			
3.6	Quality Control Testing			
	3.6.1 Physical / Chemical testing			
Activ	e Substance : LETERMOVIR			
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:			
	Crystallisation			
	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			
Activ	e Substance : RALTEGRAVIR POTASSIUM			
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 :			
	Salt Formation/Crystallisation			
3.5	General Finishing Steps			
	3.5.1 Physical processing steps : Drying			
	7 0			
	which is in direct contact with the substance)			
	2.5.2 Secondary Dealerging (placing the scaled primary peakers within an automachering			
	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		
Activ	Active Substance : SITAGLIPTIN PHOSPHATE		
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 : Salt Formation / Crystallisation		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	Drying		
	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		
Activ	e Substance : BOSENTAN 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		
	3.1.3 Salt formation / Purification steps : Crystallisation		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	Drying/Micronisation		
	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		
	e Substance : DORAVIRINE		
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 :		

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	Drying				
	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 : CARBIDOPA 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				
	3.1.3 Salt formation / Purification steps :				
	Crystallization				
3.5	General Finishing Steps				
	3.5.1 Physical processing steps :				
	Milling, Sieving, Micronization and Blending				
	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					
3.0	Quality Control Testing				
	3.6.1 Physical / Chemical testing				
A otiv	e Substance : VIGABATRIN				
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 :				
	Crystallization				
3.5	General Finishing Steps				
	3.5.1 Physical processing steps :				
	Drying and Micronisation				
	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				
	5.0.1 Thysical / Chemical testing				

2020-01-30	Name and signature of the authorised person of the Competent Authority of Ireland
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