Exm(o) (a) Senhor(a)
Representante legal da empresa
Laboratórios Basi - Indústria Farmacêutica, S.A.
Parque Industrial Manuel Lourenço Ferreira, Lote 15,
Mortágua, 3450-232, Portugal

2020-06-09 008928

Nossa referência	Vossa referência	Data
0511/000/000		

Assunto: Alteração à Autorização de Fabrico de Medicamentos veterinários

Relativamente ao assunto supramencionado e na sequência do pedido efetuado pela empresa à empresa Laboratórios Basi - Indústria Farmacêutica, S.A., cumpre-me enviar os certificados em anexo:

Autorização de Fabrico: F027/V/AF/MV/003/2014 (atualização da licença e anexo 5)

Certificado de Boas Práticas de Fabrico: BPFMV/060/003/2020

Com os melhores cumprimentos.

P/O Director-Geral

As) Fernando Bernardo

Graça Mariano
Subdiretora-Geral
Por despacho de delegação de competências nº 8140/2018
publicado no DRE, II série nº 159, de agosto de 2018

ASB

Anexo: MIA e certificado BPF

CAMPO GRANDE, Nº 50 1700-093 LISBOA TELEF. 21 323 95 00 FAX. 21 346 35 18

REPÚBLICA PORTUGUESA | AGRICULTURA

dgav Direção Geral de Alimentação e Veterinária

MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	F027/V/AF/MV/003/2014
2. Name of authorisation holder	Laboratórios Basi - Indústria Farmacêutica, S.A.
3. Address(es) of manufacturing site(s)	Laboratórios Basi - Indústria Farmacêutica, S.A., Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16, Mortágua, 3450-232, Portugal
4. Legally registered address of authorisation holder	Parque Industrial Manuel Lourenço Ferreira, Lote 15, Mortágua, 3450-232, Portugal
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 44 of Directive 2001/82/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Ms. Graca Mariano
8. Signature	Graça Mariano Subdiretora-Geral Por despacho de delegação de competências nº 8140/2018 publicado no DRE, II série nº 159, de agosto de 2018
9. Date	2020-05-29
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) [3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

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SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : Laboratórios Basi - Indústria Farmacêutica, S.A., Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16, Mortágua, 3450-232, Portugal

DUNS Number : 50-663-2296

Veterinary Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This certificate was recognized in accordance with paragraph 1 of VMP Code Law Decree n.º 314/2009 28 Oct, that republishes the Law-Decree n.º 148/2008 29 July

Graça Mariano
Subdiretora-Geral
Por despacho de delegação de competências nº 8140/2018
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Online EudraGMP, Ref Key: 46737

ANEXO 5 / ANNEX 5

Nome e morada do local de fabrico:	Laboratórios Basi - Indústria Farmacêutica, S.A.
Name and address of the site:	Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16, Mortágua, 3450-232, Portugal

Medicamentos Veterinários / Veterinary Medicinal Products

Diretor Técnico / Qualified Person

Nome(s) do(s) Diretor(es) Técnico(s) / Name(s) of Qualified Person(s)

Dr.ª Alcina Maria Sousa de Figueiredo Oliveira Cunha

O Diretor Geral de Alimentação e Veterinária,

Graça Mariano
Subdiretora-Geral
Por despacho de delegação de competências n.º 11140/2018
publicado no DRE, II série nº 159, de agosto de 2018

29-05-2020

Fernando Bernardo

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dgav Direção Geral de Alimentação e Veterinária

General Directorate of Food and Veterinary

CERTIFICATE NUMBER: ***BPFMV/060/003/2020***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Portugal confirms the following:
The manufacturer: ***Laboratórios Basi - Indústria Farmacêutica, S.A.***
Site address: ***PParque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16, Mortágua, 3450-232, Portugal***
DUNS Number: ***50-663-2296***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***F027/V/AF/MV/003/2014*** in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation:
Art. 36.º of Decree-Law n.º 148/2008, 29 of July, as amended by Decreto-Lei n.º 314/2009 of October 28

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-06*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

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.*

Graça Mariano
Subdiretora-Geral
Por despacho de delegação de competências nº 8140/2018
publicado no DRE, II série nº 159, de agosto de 2018

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Part 2

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

This certificate was recognized in accordance with paragraph 1 of VMP Code Law Decree n.º 314/2009 28 Oct, that republishes the Law-Decree n.º 148/2008 29 July

2020-05-29

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

Graça Mariano
Subdiretora-Geral
Por despacho de delegação de competências nº 8140/2018
publicado no Diário da República, 2.ª série, de 3 de julho de 2018

Ms. Graca Mariano
General Directorate of Food and Veterinary
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