ansm
Agence nationale de sécurité du médicament et des produits de santé

RÉPUBLIQUE FRANÇAISE

1. Numéro de l'autorisation *Authorisationnumber*	**MM 16/185**
2. Nom du titulaire de l'autorisation *Name of authorisationholder*	**LABORATOIRES IPHYM**
3. Adresse de l'établissement pharmaceutique *Address of pharmaceutical site*	2053 avenue Henri Schneider 69330 Jonage
4. Siège social du titulaire de l'autorisation *Legally registered address of authorisation holder*	2053 avenue Henri Schneider 69330 Jonage
5. Champ d'application de l'autorisation *Scope of authorisation*	**Fabricant** : voir annexe 1 *Manufacturer:see annex 1* **Exploitant de médicaments autres que les médicaments expérimentaux** : voir annexe 1 (distributeur) *"Exploitant" of medicinal products other than investigational medicinal products: see annex 1 (distributor)* L'activité, incluant la vente en gros et la cession à titre gratuit des produits exploités, comprend les opérations de publicité, information, pharmacovigilance, suivi des lots et, s'il y a lieu, leur retrait, ainsi que les opérations de stockage correspondantes. *The activity, including wholesale and distribution free of charge of operated products, consists in advertising, information, pharmacovigilance, batch follow-up, and if required, withdrawal operations, as well as the corresponding storage activities.* **Distributeur en gros de plantes médicinales**: voir annexe 1 (distributeur) *Wholesale distributor of medicinal plants: see annex 1 (distributor)* L'activité, incluant l'exportation des produits distribués, comprend les opérations de stockage, de contrôles ainsi que celles nécessaires pour la distribution en gros et en vrac, en sachet-doses, en fragments ou à l'état frais ou desséché de plantes médicinales mentionnées au 5° de l'article L. 4211-1. *The activity, including export of distributed products, consists of storage and control operations as well as those necessary for the wholesale distribution in bulk, in sachets, fragments or in fresh or dry state of medicinal plants stipulated in paragraph 5° de article L. 4211-1.*

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6. Base juridique de l'autorisation *Legal basis of authorisation*	Directive 2001/83/CE et Règlement CE/726/2004 Code de la santé publique *Directive 2001/83/EC and Regulation EC/726/2004* *French Public Health Code*
7. Nom du responsable de l'autorité compétente de l'Etat membre qui délivre les autorisations de fabrication / distribution *Name of Director of Competent Authority of Member state granting the wholesaling authorisation*	Dominique Martin Directeur général de l'Agence nationale de sécurité du médicament et des produits de santé *General Director of the French National Agency for Medicines and Health Products Safety*
8. Signature *Signature*	Le Directeur Adjoint de l'Inspection  Jacques MORENAS
9. Date *Date*	- 6 OCT. 2016
10. Annexes jointes *Annexesattached*	Annexe 1 et Annexe 1 (distributeur) *Annex 1 and Annex 1 (distributor)*

French National Agency for Medicines and Health Products Safety

Certificate No: 2019/BPD/132

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of France confirms the following:

The wholesale distributor: LABORATOIRES IPHYM

Site address: 2053 avenue Henri Schneider, JONAGE, 69330, France

Has been inspected under the national inspection programme in connection with authorisation number MM 16/185 in accordance with Art. 77 (1) of Directive 2001/83/ EC

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2019-09-13, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced 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.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users):

This pharmaceutical site is the subject of the injunction n° 18IPP057-INJ dated 2 August 2018, as extended by the injonction n°19MC130-INJ dated 7 November 2019 published on the ANSM website. Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2019-11-12

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

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French National Agency for Medicines and Health Products Safety

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Details of the authorisation can be found in the Union Database.

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2019/HPF/FR/305***

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 France confirms the following:
The manufacturer: ***LABORATOIRES IPHYM***
Site address: ***2053 avenue Henri Schneider, JONAGE, 69330, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***MM 16/185*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-13*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: powder - pillules - herbal tea(en)
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.8 Other solid dosage forms: powder - pillules - herbal tea(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

This pharmaceutical site is the subject of the injunction n° 18IPP057-INJ dated 2 August 2018, as extended by the injonction n°19MC130-INJ dated 7 November 2019 published on the ANSM website. Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copies of good practice certificates.

2019-11-12

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

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