



Certificate of a Medicinal Product¹

Certificado de Medicamento¹

Certificat de Médicament¹

This Certificate conforms to the format recommended by the World Health Organization. (Explanatory notes attached) /
El presente certificado se adapta al formato recomendado por la Organización Mundial de la Salud. (Se adjuntan notas explicativas) /
Ce Certificat est conforme à la présentation recommandée par l'Organisation Mondiale de la Santé. (Voir notes explicatives ci-jointes)

No. of Certificate / N° de certificado / N° du certificat: **16/20/148457**

Exporting (Certifying) region / Región exportadora (que certifica) / Région d'exportation (certificateur) :
European Union / Unión Europea / Union Européenne :

Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and United Kingdom.

Bélgica, Bulgaria, Chequia, Dinamarca, Alemania, Estonia, Irlanda, Grecia, España, Francia, Croatie, Italia, Chipre, Letonia, Lituania, Luxemburgo, Hungría, Malta, Países Bajos, Austria, Polonia, Portugal, Rumanía, Eslovenia, Eslovaquia, Finlandia, Suecia y Reino Unido.

Belgique, Bulgarie, Tchèque, Danemark, Allemagne, Estonie, Irlande, Grèce, Espagne, France, Croatie, Italie, Chypre, Lettonie, Lituanie, Luxembourg, Hongrie, Malte, Pays-Bas, Autriche, Pologne, Portugal, Roumanie, Slovénie, Slovaquie, Finlande, Suède et Royaume-Uni.

As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period /
Depuis le 1er février 2020, le Royaume-Uni n'est plus un État membre de l'UE. Cependant, il continue d'être soumis au droit de l'UE pendant la période transitoire /
A partir del 1 de febrero de 2020, el Reino Unido dejará de ser Estado miembro de la UE. Sin embargo, el Derecho de la UE se seguirá aplicando en el Reino Unido durante el período de transición

Importing (requesting) country / País importador (solicitante) / Pays importateur (sollicitant):

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- 1 Name and pharmaceutical form of the product / Nombre y forma farmacéutica del medicamento /
Dénomination et forme pharmaceutique du médicament:

Zavicefta Powder for concentrate for solution for infusion

- 1.1 Active substance(s)² and amount(s) per unit dose or unit volume³:
Principio(s) activo(s)² y cantidad(es) por unidad de dosis o unidad de volumen³:
Substance(s) active(s)² et quantité(s) par unité de dose ou unité de volume³:

Each vial contains ceftazidime pentahydrate equivalent to 2 g ceftazidime and avibactam sodium equivalent to 0.5 g avibactam; 10 vials

For complete composition including excipients, see attached. ⁴ / Para la composición completa incluidos los excipientes, véase información anexa. ⁴ / La composition complète du médicament, y compris les excipients, voir annexe. ⁴

- 1.2 Is this product subject to a Community Marketing Authorisation? ⁵
¿Está sujeto este medicamento a una autorización de comercialización comunitaria? ⁵
Ce médicament fait-il l'objet d'une autorisation communautaire de mise sur le marché? ⁵

yes

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- 1.3 Is this product actually on the market in the exporting region?
¿Se encuentra este medicamento en el mercado de la región exportadora?
Ce médicament est-il actuellement commercialisé dans la région exportatrice?

yes

- 2.1 Number in the Community Register of Medicinal Products ⁷ and date of issue:
Número de autorización de comercialización comunitaria ⁷ y fecha de emisión:
Numéro au registre communautaire de mise sur le marché ⁷ et date de délivrance:

EU/1/16/1109/001, 24.6.2016

- 2.2 Community Marketing Authorisation Holder (name and address):
Titular de la autorización de comercialización comunitaria (nombre y dirección):
Titulaire de l'autorisation communautaire de mise sur le marché (nom et adresse) :

Pfizer Ireland Pharmaceuticals, Operations Support Group, Ringaskiddy, County Cork, Ireland.

- 2.3 Status of the Community Marketing Authorisation Holder: ⁸
Estatus del titular de la autorización de comercialización comunitaria: ⁸
Statut du titulaire de l'autorisation communautaire de mise sur le marché : ⁸

c

- 2.3.1 For categories (b) and (c) the name and address of the manufacturer producing the pharmaceutical form is: ⁹
Para las categorías (b) y (c), el nombre y dirección del fabricante que produce la forma farmacéutica es: ⁹
Pour les catégories (b) et (c), nom et l'adresse du fabricant de la forme pharmaceutique considérée : ⁹

ACS Dobfar S.p.A., Via Alessandro Fleming, 2, 37135 Verona, Italy.

- 2.4 Is the European Public Assessment Report (EPAR) appended? ¹⁰
¿Se adjunta el informe europeo público de evaluación (EPAR)? ¹⁰
Un rapport européen public d'évaluation (EPAR) est-il annexé ? ¹⁰

no

- 2.5 Is the attached, officially approved product information included in the Community Marketing Authorisation? ¹¹
¿Se incluye la información sobre el medicamento adjunto en la autorización de comercialización comunitaria? ¹¹
L'information sur le médicament, officiellement approuvée, fait-elle partie de l'autorisation communautaire de mise sur le marché ? ¹¹

yes

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- 2.6 Applicant for the Certificate, if different from the Community Marketing Authorisation Holder (name and address): ¹²
Solicitante del Certificado, si es diferente del titular de la autorización de comercialización comunitaria (nombre y dirección): ¹²
Demandeur du Certificat, s'il est autre que le titulaire de l'autorisation communautaire de mise sur le marché (nom et adresse) : ¹²

3. Does the Certifying Authority arrange for periodic inspections of the manufacturing site in which the pharmaceutical form is produced?
¿La autoridad certificadora, dispone la inspección periódica de la planta de fabricación en que se produce la forma farmacéutica?
L'autorité certificatrice organise-t-elle des inspections périodiques de l'usine de production de la forme pharmaceutique?

yes

If no or not applicable, proceed to question 4 / Si no o no aplicable, pase a la pregunta 4 / Si la réponse est non ou sans objet, passer à la question 4.

- 3.1 Periodicity of routine inspections: **Frequency of inspections is determined on risk-based approach.**
Periodicidad de las inspecciones de rutina: **La frecuencia de las inspecciones esta basada en función del riesgo.**
Périodicité des inspections de routine: **L'évaluation du risque détermine la fréquence des inspections.**

- 3.2 Has the manufacture of this type of pharmaceutical form been inspected?
¿Se ha inspeccionado la fabricación de este tipo de forma farmacéutica?
La fabrication de ce type de forme pharmaceutique a-t-elle fait l'objet d'une inspection?

yes

- 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? ¹⁵
¿Se adaptan las instalaciones y procedimientos a las GMP recomendadas por la Organización Mundial de la Salud? ¹⁵
Est-ce que l'établissement pharmaceutique est conforme aux BPF recommandées par l'Organisation Mondiale de la Santé ? ¹⁵

yes

4. Does the information submitted by the applicant satisfy the Certifying Authority on all aspects of the manufacture of the product undertaken by another party? ¹⁶
¿La información presentada por el solicitante satisface a la autoridad de certificación en relación a todos los aspectos de la fabricación del medicamento realizada por terceros? ¹⁶
Les informations fournies par le demandeur satisfont-elles aux exigences des autorités certificatrices sur tous les aspects de la fabrication du médicament pris en charge par une tierce partie ? ¹⁶

yes

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Address of the Certifying Authority / Dirección de la autoridad certificadora / Adresse de l'autorité certificatrice :

European Medicines Agency
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

Telephone / Teléfono / Téléphone: **+31 (0)88 781 6000**
Facsimile / Fax / Télécopie:
E-mail / Correo electrónico/ Courrier électronique: **certificate@ema.europa.eu**

Name of authorised person / Nombre de la persona autorizada / Nom de la personne autorisée:

Signature / Firma / Signature: **Luc Van Santvliet**
Digitally signed by
Luc Van Santvliet
Date: 2020.08.31
15:57:50 +02'00'

Stamp and date / Sello y fecha / Tampon et date: **31.8.2020**



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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
This public document
2. has been signed by **L. Stuijzand**
3. acting in the capacity of official of the Ministry of
Foreign Affairs
4. bears the seal/stamp of aforesaid Ministry

Certified

5. in Rotterdam
6. on 15-10-2020
7. by the registrar of the district court of Rotterdam
8. no. 20 6245



10. Signature:

W.N. Kole

wnkole

Explanatory notes

- ¹ This Certificate, which is in the format recommended by WHO, establishes the status of the medicinal product and of the applicant for the Certificate in the exporting region at the time of issue. It is for a single product at a given point in time since manufacturing arrangements and approved information for different pharmaceutical forms and different strengths can vary.
- ² Whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names are used.
- ³ The formula (complete composition) of the pharmaceutical form is appended.
- ⁴ Provision of the details of quantitative composition is attached on request of the Community Marketing Authorisation Holder.
- ⁵ When applicable, details are appended of any conditions or restrictions applied to the supply and use of the product that is entered into the Community Marketing Authorisation.
- ⁶ Not applicable.
- ⁷ Indicated, when applicable, if the Community Marketing Authorisation has been granted under exceptional circumstances, conditional approval or if the product has not yet been approved.
- ⁸ The person responsible for placing the product on the market:
(a) manufactures the pharmaceutical form;
(b) packages and/or labels a pharmaceutical form manufactured by an independent company; or
(c) is involved in none of the above.
- ⁹ This information can only be provided with the consent of the Community Marketing Authorisation Holder or, in the case of non-registered products, the applicant. Non-completion of this section (2.3.1) indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the Community Marketing Authorisation. If the production site is changed, the Community Marketing Authorisation has to be updated or it is no longer valid.
- ¹⁰ This refers to the document that summarises the technical basis on which the product has been authorised.
- ¹¹ This refers to the product information which forms a part of the Community Marketing Authorisation, such as the Summary of Product Characteristics (SPC).
- ¹² In this circumstance, permission for issuing the Certificate is required from the Community Marketing Authorisation Holder. This permission has to be provided to the European Medicines Agency by the applicant.
- ¹³ If applicable the reason why the medicinal product does not have a Community Marketing Authorisation, e.g.:
(a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the exporting region;
(b) the product has been reformulated with a view to improving its stability under tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for use in medicinal products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active substance;
(e) any other reason, as specified.
- ¹⁴ "Not applicable" means the manufacture is taking place in a region other than that issuing the Certificate and inspection is conducted under the aegis of the country of manufacture.
- ¹⁵ The requirements for good practices in the manufacture and quality control of medicinal products referred to in the Certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No 822, 1992, Annex 1).
- ¹⁶ This section is to be completed when the Community Marketing Authorisation Holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the Certifying Authority with information to identify the contracting parties responsible for each stage of manufacture of the pharmaceutical form, and the extent and nature of any controls exercised over each of these parties.



**STATEMENT OF QUANTITATIVE COMPOSITION
DECLARACIÓN DE COMPOSICIÓN CUANTITATIVA
ÉNONCÉ DE LA COMPOSITION QUANTITATIVE**

1. Name and pharmaceutical form of the Medicinal Product:
Nombre y forma farmacéutica del medicamento:
Dénomination et forme pharmaceutique du médicament:

Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion

2. Number(s) in the Community Register of Medicinal Products:
Número(s) de autorización de comercialización comunitaria:
Numéro(s) au registre communautaire de mise sur le marché:

EU/1/16/1109/001

3. Qualitative and quantitative composition of the Medicinal Product:
Composición cualitativa y cuantitativa del medicamento:
Composition qualitative et quantitative du médicament:

Active ingredient(s): Principio(s) activo(s): Substance(s) active(s):	Quantities and units: Cantidades y unidades: Quantités et unités:		
<i>Avibactam sodium</i>	<i>543.5</i>	<i>milligrammes</i>	<i>Active</i>
<i>Ceftazidime pentahydrate</i>	<i>2329.7</i>	<i>milligrammes</i>	<i>Active</i>
Other ingredient(s): Otros ingrediente(s): Excipient(s):	Quantities and units: Cantidades y unidades: Quantités et unités:		
<i>Sterile sodium carbonate</i>	<i>232.9</i>	<i>milligrammes</i>	<i>Excipient</i>

