HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Certificado de un producto farmacéutico

Este certificado se ajusta al modelo recomendado por la Organización Mundial de la Salud.

País exportador (certificador): **Irlanda**

País importador (solicitante): **Colombia**

1. Nombre y forma farmacéutica del producto:

Metopirone 250mg Capsules, soft

1.1 Principios(s) activo(s) y cantidad(es) por unidad de dosis:

METYRAPONE **250 mg**

Para la composición completa inclusive excipientes, ver anexo.

1.2 Está este producto autorizado para ser puesto en el mercado en el país exportador?
Si

1.3 ¿Está este producto realmente en el mercado del país exportador?
Si

Si la respuesta a 1.2. es sí, continuar con la sección 2A y omitir la sección 2B. Si la respuesta a 1.2. es No omitir la sección 2A y continuar con la sección 2B

2A.1 Número de la autorización del producto y fecha de emisión:

PA 1166/003/001 primera autorización: 3 de Febrero de 2012

2A.2 Titular de la autorización del producto (nombre y dirección):

Laboratoire HRA Pharma
200 Avenue de Paris
92320 CHATILLON
Francia

2A.3 Condición del titular de la autorización del producto: **c**

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire

2A.3.1 Para las categories b y c, el nombre y la dirección del fabricante que produce la forma farmacéutica es:

Catalent Germany Eberbach GmbH,
Gammelsbacher Str. 2,
Germany.

2A.4 ¿Se adjunta "summary basis for approval"?
N/a

2A5. La información de las condiciones de aprobación del producto que se adjunta ¿es completa y conforme con la autorización?
Si

2A.6 Solicitante del certificado, si es diferente del titular de la autorización (nombre y dirección)

2B.1 Solicitante del certificado (nombre y dirección):

2B.2 Condición del solicitante:
(Marcar la categoría que corresponda según se define en la nota 8)

2B.2.1 Para las categorías (b) y (c), el nombre y dirección del fabricante que produce la forma farmacéutica es:

2B.3 ¿Por qué no se dispone de la autorización de comercialización?
(Marcar según corresponda)

2B.4 Comentarios:

3. La Autoridad certificadora, ¿efectúa inspecciones periódicas de la planta de fabricación en la que se produce la forma farmacéutica?
No

3.1 Periodicidad de las inspecciones rutinarias (años):
No procede

3.2 ¿Se ha inspeccionado la fabricación de este tipo de forma farmacéutica?
No procede

3.3 ¿Las instalaciones y procesos cumplen con las Buenas Prácticas de Manufactura como recomienda la Organización Mundial de la Salud?
No procede

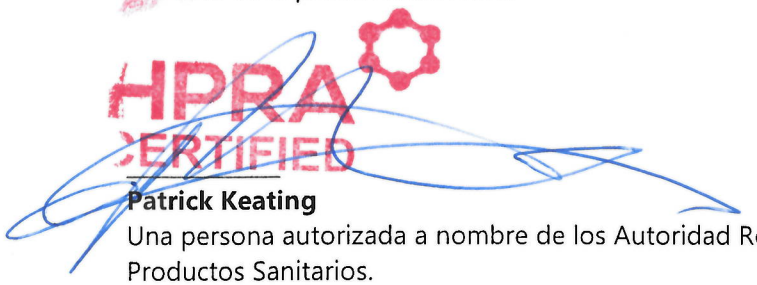
An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire

4. ¿La información presentada por el solicitante satisface a la Autoridad certificadora en todos los aspectos de la fabricación del producto?
Si

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Ireland

Telefono: 01-676-4971 **Fax:** 01-676-4061

Nombre de la person autorizada:



Patrick Keating
Una persona autorizada a nombre de los Autoridad Reguladora Irlandesa de Medicamentos y Productos Sanitarios.
Compliance Department
24th Enero 2020

N.B. La información contenida en el certificado es válido y verdadero reflejo de la más reciente información disponible referente a la autorización de producto disponible en el momento de su emisión.

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/País:	**IRELAND**
This public document Le présent acte public / El presente documento público	
2. has been signed by a été signé par ha sido firmado por	Mr. Patrick Keating
3. acting in the capacity of agissant en qualité de quien actúa en calidad de	Health Products Regulatory Authority
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	N/A

Certified
Attesté / Certificado

5. at à / en	Dublin	**6. the** le / el día	10/02/2020
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	1842102020		
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** Signature: Firma: MSewell		

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. To verify the issuance of this Apostille, see www.authentications.dfat.ie

516887

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   a. manufactures the dosage form;
   b. packages and/or labels a dosage 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 product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section 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 product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    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 pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product 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 drugs 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 product-licence 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 finished dosage form, and the extent and nature of any controls exercised over each of these parties.