Issued to:

<Applicant Name>

<Applicant Address>

Free sale certificate number: <insert here>

Certificate number: <insert here>

**CERTIFICATE OF FREE SALE**

To Whom It May Concern:

The Health Products Regulatory Authority, Ireland, being the Competent Authority for the licensing of the manufacture, preparation, and sale of medicinal products in Ireland in accordance with the requirements of Directive 2001/83/EC and Directive 2001/82/EC as amended by Directive 2004/28/EC; and in exercise of the powers conferred on it under the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007), as amended, and the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007), as amended; hereby certifies that:

1. The medicinal product named and described <in the schedule below\*/in the attached certified schedule\*> has been authorised to be placed on the market for use in this country under the marketing authorisation number <*insert PA/VPA number>* granted on <*insert date of authorisation>.*
2. Exportation of the product is not prohibited.

\*SCHEDULE

<Product name, dosage form, dose, active ingredients, PA/VPA number ---/--/->

e.g. Ampicillin Capsules 500mg, active ingredient Ampicillin, P.A. 298/10/4

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<name>

A person authorised in that behalf by the Health Products Regulatory Authority

<position>

<department>

<date>

\*SCHEDULE

Product name:

Composition

Active Ingredient Percent (w/v)

mg/ml

Inactive Ingredients Percent (w/v)

mg/ml

Other Ingredients Percent (w/v)

mg/ml

Capsule Shell Composition

Indications

Dosage

How product is supplied

Marketing restrictions

Shelf life

\**delete as appropriate*