# CERTIFICATE OF A PHARMACEUTICAL PRODUCT1

This certificate conforms to the format recommended by the World Health Organization

Exporting (Certifying) country: **Denmark**

Importing (requesting) country: **Country**

1. Name and dosage form of the product: 2

 Name and dosage form of product

1.1 Active ingredient(s)2 and amount(s) per unit dose or unit volume: 3

 Active ingridient and amount per unit

 For complete composition including excipients, see attached4

* 1. Is this medicinal product subject to a Marketing Authorisation or an Export License (the Export License is a voluntary Danish authorisation for pharmaceutical products intended for export only or for medicinal products not regarded as such in Denmark)? 5

*Marketing Authorisation:* ***[ ]  Yes***

or

*Export License:* ***[ ]  Yes***

* 1. Is this product actually on the market in Denmark?

***[ ]  Yes*** ***[ ]*** ***No******[ ]  Not known***

2.1 Number of Marketing Authorisation / Export License7 and date of issue:

 Number of marketing authorisation

2.2 Marketing Authorisation Holder / Export License Holder (name and address):

 Name of MAH/ELH

 Adress, postcode, city, country

2.3 Status of Marketing Authorisation Holder / Export License Holder: 8

[ ]  ***a*** [ ]  ***b*** [ ]  ***c*** [ ]  ***d***

2.3.1 For categories b, c and d the name and address of the manufacturer producing the dosage form is: 9

* 1. Is the European Public Assessment Report (EPAR) appended? 10

[x]  ***No***

2.5 Is the attached, officially approved product information included in the Marketing Authorisation / Export License? 11

[ ]  ***Yes***[ ]  ***No***[ ] ***Not provided/not attached***

2.6 Applicant for certificate, **if different** from the Marketing Authorisation Holder / Export License Holder (name and address): 12

3. Does the Certifying Authority arrange for periodic inspections of ‘the manufacturing site - including release’ (according to point 2.3.a / b) or ‘the manufacturing site - by release only’ (according to point 2.3.c)? 14

 *Manufact. site, incl. release* [ ]  ***Yes***[ ]  ***No***[ ]  ***Not applicable***

*Manufact. site, release only* [ ]  ***Yes***[ ] ***No*** [ ]  ***Not applicable***

3.1 Periodicity of routine inspections: ***Every 2 years, but not exceeding 3 years***

* 1. Has the manufacturer of this type of dosage form been inspected?

[ ]  ***Yes*** [ ]  ***No***[ ]  ***Not applicable***

3.3. Do the facilities and operations in Denmark conform to GMP as recommended by the World Health Organization? 15

[x]  ***Yes***

1. 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

 [ ]  ***Yes*** [ ]  ***No - If no, justification:***