# 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. 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 pharmaceutical 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

 [x]  ***No***

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

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

2.1 Applicant for the Certificate (name and address):

 Name of applicant for the certificate

 Adress, postcode, city, country

* 1. Status of the applicant: 8

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

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

2.3 Why is a Marketing Authorisation / Export License lacking?

[ ]  ***Not required*** [ ]  ***Not requested***

2.4 Remarks:13

3. Does the Certifying Authority arrange for periodic inspections of ‘the manufacturing site - including release’ (according to point 2.2.a / b) or ‘the manufacturing site - by release only’ (according to point 2.2.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***

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? 16

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