EDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization (General Instructions and explanatory notes attached)

No. of Certificate : 000004 23-12-13
Exporting (certifying) country : **BELGIUM**
Importing (requesting) country :

1. Name and dosage form of product :

CONCERTA 36 mg prolonged release tablets

1.1 Name and amount of the active[2] and inactive ingredients per unit dose[3] :

ACTIVE INGREDIENT

Methylphenidate hydrochloride	**36**	**mg**

INACTIVE INGREDIENTS

[redacted]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **yes**
1.3 Is this product actually on the market in the exporting country? **yes**
Approved shelf-life: 3 years
2A.1 Number of product licence[7] and date of issue : **BE 242697 date : 16/12/2002**
2A.2 Product licence holder : **JANSSEN-CILAG NV, Antwerpseweg 15-17, B-2340 Beerse, Belgium**
2A.3 Status of product licence holder[8] :
☐ a / ☐ b / ☒ c

ategories b and c the name and address of the manufacturer producing the dosage form is[9] :

Name and address of the manufacturer(s) of the finished product :
Alza Corporation, 700 Eubanks Drive Vacaville, CA 95688, USA
Anderson Brecon, Inc., 4545 Assembly Drive, Rockford, IL 61109, USA
Janssen Ortho, L.L.C., HC 02 Box 19250, State Road 933 Km 0.1, Mamey Ward, Gurabo, Puerto Rico 00778-9629
Name and address of the packager(s) :
McGregor Cory Limited, Middleton Road, Banbury, Oxon, OX164RS, UK +
Anderson Brecon, Inc., 4545 Assembly Drive, Rockford, IL 61109, USA
Janssen-Cilag GmbH, Johnson & Johnson Platz 1, 41470 Neuss, Germany
Janssen Ortho, L.L.C., HC 02 Box 19250, State Road 933 Km 0.1, Mamey Ward, Gurabo, Puerto Rico 00778-9629
Name and address of the manufacturer(s) responsible for the lotanalysis(QC) :
Alza Corporation, 700 Eubanks Drive Vacaville, CA 95688, USA
Janssen Pharmaceutica, Turnhoutseweg 30, 2340 Beerse, Belgium
Name and address of the manufacturer(s) responsible for the administrative release:
(responsible for batch-release in the EEA according Article 40 and Article 51 of guideline2001/83EC):
Janssen Pharmaceutica NV, Turnhoutseweg 30, 2240 Beerse, Belgium

2A.4 Is summary basis of approval appended ?[10] **no**
2A.5 Is the attached, officially approved product information complete and consonant with the licence ?[11] **yes**
2A.6 Applicant for certificate, if different from licence holder[12] :
JANSSEN PHARMACEUTICA NV, Turnhoutseweg 30, 2340 Beerse, Belgium
2B Not applicable [6,13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced14? **yes (only for Janssen Pharmaceutica NV, Belgium)**
3.1 Periodicity of routine inspections (years) : **2 (only for Janssen Pharmaceutica NV, Belgium)**
3.2 Has the manufacture of this type of dosage form been inspected ? **yes (only for Janssen Pharmaceutica NV, Belgium)**
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization[15] ?**yes (only for Janssen Pharmaceutica NV, Belgium)**

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16] ? **yes**

Address of certifying authority:	FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS, EUROSTATION II, Victor Hortaplein 40 bus 40, 1060 BRUSSELS (BELGIUM)	
Telephone n°: +32 2 524.82.97 / +32 2 524.82.98 / +32 2 524.80.61		Fax n°: +32 2 524.83.01
Date: 23 DEC. 2013 Stamp: Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)	afmps fagg	Name of authorized person: Xavier De Cuyper Chief Executive Officer Philippe DE BUCK DG Inspection Head of Division Authorisations

2013.J.23/IP

Explanatory notes

This certificate, which is

guidelines for generation by

are suitable for handwritten.

type rather than handwritten.

tional sheets should be appended.

s for full instruc

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Pays: Belgique
2. Le présent acte public a été signé par: De Buck, Philippe
3. Agissant en qualité de: Inspecteur
4. Est revêtu du sceau / timbre de: SPF Affaires sociales et de la Santé publique
   Brussels

Attesté

5. A Bruxelles 6. Le: 03/01/2014
7. Par le Service public fédéral Affaires étrangères, Commerce extérieur et Coopération au Développement
8. Sous le n°: **9805140103782593**
9. Sceau/timbre:
10. Signature:

Jan Van de Velde