Health Care Inspectorate - Pharmaceutical Affairs

Certificate No: NL/G 17/2000916

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of Netherlands confirms the following:

The active substance distributor Duchefa Farma B.V.

Site address: A. Hofmanweg 71, HAARLEM, 2031BH, Netherlands

has been inspected in accordance with Art . 111(1) of Directive 2001/83/EC transposed in the following national legislation: Art. 100 of the Medicines Actand in connection with registration no 6232 API

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2017-07-06, it is considered that it complies with the principles of Good Distribution Practice for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2017-09-04

Name and signature of the authorised person of the Competent Authority of Netherlands

i/a

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport
Rijksoverheid

Ms Kai Liang

Health Care Inspectorate - Pharmaceutical Affairs
Tel: +31 881205 000

k.liang@igz.nl