# GMP Audit Certificate

We hereby certify that a Good Manufacturing Practices (GMP) audit was completed, in the production plant that the company:

## NEKICESA

has in Planta Sur - Crta. Navalcarnero-Chinchón, Km 21.2, 28971 Griñón (Madrid) and Planta Norte – Parque 9, Pol. Ind. La Cruz, 28130 Valdeolmos-Alalpardo (Madrid). The audit was performed on July 1st and 2nd 2014.

The regulatory frame is established by the EU Directive 2001/83/EC (its amendments 2004/27/EC and 2011/62/EC). The GMP assessment has been done taking as reference the ISO 15378:2011: "Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP)".

The audit was carried out following the requisites set forth in the current version of the "Intercompany Protocol for performing 3rd Party Audits to Suppliers".

The results of this audit are described in a ***full report, filed by the Association***. The report is available to the interested parties, and bound by the terms and conditions of confidentiality, agreed with the audited company.

The validity of this certificate is established in 5 years, according the audit report shelf-life.

Signed in Barcelona by:

Digitally signed by NOMBRE CAYON COSTA EDUARD - NIF 36041693A
Reason: Document issuance
Date: 2014.09.19 14:03:12 +02'00'

Dr. Eduard Cayón
*Forum Auditorías Director*

***This document has been electronically signed. The signature is certified by an official entity (click on the signatures for more details)***





Asociación Forum Auditorias
Rda. General Mitre, 147, Entlo. 2ª 08022 Barcelona Spain
Phone: + 34 934178065 Fax: + 34 934340314
e-mail: asociacion@forumauditorias.org
forumauditorias.org