

GMP Audit Certificate

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

PARTICLE DYNAMICS INTERNATIONAL, LLC

has in 2629 S. Hanley Road, St. Louis (MO) 63144, USA. The audit was performed on November 11th, 2015.

The related regulatory frame is established by the EU Directive 2001/83/EC (and amendments 2004/27/EC and 2011/62/EC). The GMP assessment has been done taking as reference the EU Directive 2003/94/EC, and the correspondent guidance EUGMP Part II (ICH Q7).

The audit was carried out following the Accredited ISO 17020 Quality System and 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 3 years, according to the audit report shelf-life.

Signed in Barcelona by:



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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)*



ISO 17020 GMP Inspection Body

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