

GMP Audit Certificate

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

PURITY CHEMICALS S.L.

has in Av. Tren Expreso, Parcelas 82-84, 34200 Venta de Baños (Palencia), SPAIN. The audit was performed on May 23rd, 2017.

The regulatory frame is established by the EU Directive 2001/83/EC (including its amendments 2004/27/EC and 2011/62/EC) and the GMP assessment has been done taking as reference 2006 IPEC - PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

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 by:

Dr. Eduard Cayón Director

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



