

GMP Audit Certificate

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

ALPAVIT

has in Kemptener Straße 17 - 24, 87493 Lauben / Allgäu, Germany. The audit was performed on November 22nd 2018.

The related regulatory frame is established by the EU Directive 2001/83/EC (including its amendments 2004/27/EC and 2011/62/EU). The GMP assessment has been done taking as reference the 2017 IPEC - PQG Good Manufacturing Practices Guide for pharmaceutical excipients for the base level required.

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)