

**AUDIT GMP PHARMA S.L.**

Your reliable partner for 2<sup>nd</sup> and 3<sup>rd</sup> GMP Audits

# **AUDITGMP Pharma, S.L.**

**API GMP Compliance Evaluation**  
Active Pharmaceutical Ingredients GMP

**Components GMP Compliance Evaluation**  
Pharmaceutical Primary Packaging and Excipients GMP

**FDF GMP Compliance Evaluation**  
Final Dose Forms GMP



**AUDITGMP Pharma SL**

Via Augusta, 213 08021 BARCELONA (SPAIN)  
Phone +34.932412425 Fax +34.932414118  
[auditgmp@auditgmp.net](mailto:auditgmp@auditgmp.net)

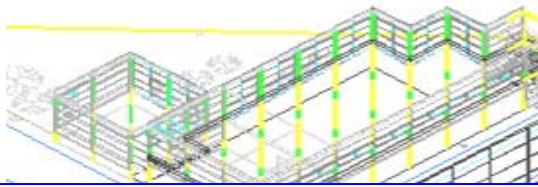
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**FACILITIES, SYSTEMS, PROCESSES Evaluation**

**INTERNAL GMP AUDIT**

**AUDIT to PREPARE INSPECTIONS for:**

- EDQM (CEP/COS)
- FDA
- CLIENTS

**SUPPLIERS AUDIT PROGRAM:**

- APIS
- INTERMEDIATES
- FINISH PRODUCT
- EXCIPIENTS
- PACKAGING MATERIAL
- BROKERS



Annex VI to Regulation (EC) No 1831/2003  
**AF-CSP (09) 4**  
 TEMPLATE OF A CERTIFICATE OF SUITABILITY CORRESPONDING TO  
 CONCLUSION 4  
 WHERE ALL FACTORS ARE CONTROLLED BY THE MONOGRAPH

Certificate No. 00-CEP-XXXX-Revision 0

Name of the substance:  
XXX

Name of holder:  
XXX

Site of production:  
XXX

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site of production mentioned above, XXX, we certify that the quality of the substance is suitably controlled by monograph XXX (Ph. Eur. 31st Ed., no. XXX, 2000).

...ected and their limits are set as:

...ed every five years or after any significant modification of the the quality, safety or efficacy of the product or require monograph.

...ke place in accordance with Good Manufacturing Practice and the.

...as will render this certificate void.

...ramework of the procedure established by the European Union AF-CSP (09) 4) for a period of five years starting from the date of the entry into force of the provisions of Directive 75/318/EEC amended and the related guidelines.

...ch analysis certificate.

Signature

*AUDIT GMP is a firm exclusively devoted to third party Quality Audits in pharmaceutical and regulated markets, with a team of very experienced (in Production, Quality Control and Quality Assurance) highly recognised senior auditors.*

*Having its own Quality system in place, AUDIT GMP offers assessment GMP compliance audits (European and FDA) and mock inspections to prepare EDQM, FDA or clients audits. International supplier audits.*

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