

AUDIT TYPES AND REFERENCES

| Type of audit | Acceptance Criteria References |
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| Active Substances Manufacturing (APIs) | <ul style="list-style-type: none"> ▶ Directive 2003/94/CE. EUGMP Part II (ICH Q7A) ▶ LAW 29/2006, dated July 26th, on the guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July, 2006). ▶ CPMP, EMEA, ICH, FDA Guides |
| Excipients Manufacturing | <ul style="list-style-type: none"> ▶ Directive 2003/94/CE. EUGMP Part II ▶ LAW 29/2006, dated July 26th, on guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ GMP for bulk pharmaceuticals excipients, IPEC ▶ Royal Pharmaceutical Society of Great Britain. "PS9100:2002 Pharmaceutical excipients"(2002) ▶ WHO "Scheme for Certification of Pharmaceutical Starting Materials" ▶ CPMP, EMEA, ICH, FDA Guides |
| Packaging material manufacturing | <ul style="list-style-type: none"> ▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ ISO 9001 2000. ▶ ISO 15378. Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP). ▶ Code of Pharmaceutical Supplier Practices. The Institute of Quality Assurance. Pharmaceutical Quality Group. ▶ Quality Assurance of Pharmaceutical and Packaging Materials. Cantor Verlag Aulendorf Edition (ECV) |
| Finished and intermediate products manufacturing | <ul style="list-style-type: none"> ▶ Directive 2003/94/CE. EUGMP Part I ▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ PIC'S Guides ▶ PIC/S, CPMP, EMEA, ICH, FDA Guides |
| Computer System Design and Development | <ul style="list-style-type: none"> ▶ Directive 2003/94/CE. EUGMP Part I, Anexo 11 ▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ PIC/S Guides, GAMP Forum |
| Chemical and microbiological analysis | <ul style="list-style-type: none"> ▶ Directive 2003/94/CE. EUGMP ▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ CPMP, EMEA, ICH, FDA Guides |
| Logistics and warehouses | <ul style="list-style-type: none"> ▶ Guia de Bones Pràctiques en el Transport de Medicaments. versió 1. Set-05. Generalitat de Catalunya. Departament de Salut. Direcció General de Recursos Sanitaris. ▶ Directive 2003/94/CE. EUGMP ▶ LAW 29/2006, dated July 26th, about guarantees and rational use of Pharmaceutical drugs and products. (BOE 178, 27th July 2006). ▶ Royal Decree 2259/1994 ▶ CPMP, EMEA, ICH, FDA, WHO Guides |