



EGA *fact sheet* on generic medicines

Good Manufacturing Practice Guarantees Quality Generic Medicines

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Like all pharmaceutical manufacturers, generic medicines producers must comply with the strict rules of Good Manufacturing Practice. GMP ensures that all medicines - generic, OTC (ie, non prescription) and originator alike - are produced consistently and controlled to stringent standards of quality in accordance with current legislation.

GMP regulations¹ require generic medicines laboratories, manufacturers, processors, and packagers to take proactive measures to ensure that their products are safe and pure. The same rules apply to the production of generic medicines as to originator medicines.

GMP is designed to guarantee patients the quality of pharmaceutical products, and to eliminate the possibility of contamination. A generic medicines company's GMP quality control system must encompass the entire manufacturing process. To be GMP certified, a company must show that it maintains appropriate facilities and equipment, and that it follows approved procedures for all its operations ranging from ordering and receiving raw

materials to production, packaging, storage, dispatch and delivery.

GMP regulations govern areas such as recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. GMP also requires thorough documentation for every aspect of the development, testing, production and logistics process to allow for traceability and the eventual recall of a product in case a problem should arise.

In addition, generic medicines manufacturers are required to ensure that the active pharmaceutical ingredients (APIs) and other materials used in their products meet EU quality standards. GMP for APIs must be demonstrated during the application for marketing approval via a declaration of the so-called Qualified Person (QP) and by making available to the inspectors the evidence on which this declaration is based. API producers are also subject to on-site EU

inspection regardless of where they are located throughout the world.²

Rightly, generic manufacturers, along with originator companies, must establish highly effective systems to meet the demands of Good Manufacturing Practice. Compliance with GMP is ensured through regular internal and external audits and official inspection by the medicines regulators. Without the proper GMP standards, the regulators will not authorise a generic medicine for use by the public.

¹ **Principles and Guidelines for GMP:** Directive 2003/94/EC (Official Journal L262, 14/10/2003 p 22-26).

² **EU GMP Rules:** Eudralex – The Rules Governing Medicinal Products in the European Union, Volume 4: Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice ec.europa.eu/enterprise/pharmaceuticals/eudralex/

³ **Concerning Inspections of APIs,** see ICH Q9 Quality Risk Management, EMEA, 19 January 2006. Available on-line from the European Medicines Agency (EMA) at: www.emea.europa.eu/Inspections/docs/ICHQ9Step4QRM.pdf.

Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.