

## Good Manufacturing Practices (GMP) Statement for Quality Assurance in FARMA Labels

## **OBJECTIVE**

At TOMPLA, we are committed to maintaining the highest standards of quality, safety, and effectiveness in the manufacturing and supply of labels intended for the pharmaceutical sector. Our Good Manufacturing Practices (GMP) Policy establishes the guidelines and principles that all employees must follow to ensure compliance with applicable regulations and standards, as well as customer satisfaction and the well-being of end users.

## **PRINCIPLES**

**Quality and Safety:** We implement rigorous quality controls at all stages of production. This includes thorough supplier selection and evaluation, raw material inspection, process validation, in-line and off-line quality controls, and the use of equipment that ensures the integrity and consistency of our products.

**Documentation and Process Control:** We maintain accurate and complete documentation of all manufacturing procedures and processes. This includes raw material specifications, manufacturing procedures, quality control methods, and production records. We establish an effective change control system to ensure that all modifications are properly evaluated, authorized, and documented.

**Training and Competence:** Our staff receives continuous training in GMP, safe manufacturing practices, and quality. We promote competence and awareness of the importance of their role in the manufacturing of labels intended for the pharmaceutical sector.

**Risk Management:** We identify and assess the risks associated with our manufacturing operations and take the necessary measures to mitigate them. We implement appropriate controls and monitoring systems to prevent deviations and ensure the quality of our products. We foster a culture of incident and deviation reporting and take corrective actions effectively.

**Continuous Improvement:** We continuously seek opportunities to improve our processes, systems, and products. We conduct periodic reviews of our GMP performance, establishing key performance indicators and improvement objectives. We encourage active participation of personnel in identifying and implementing improvements, promoting a culture of continuous improvement throughout the organization.

This Good Manufacturing Practices (GMP) policy is mandatory for all TOMPLA personnel. Senior management is committed to providing the necessary resources and support to implement and maintain this policy and to ensure its compliance in all areas of the company.

Andre Wienstroer Director General

Alcalá de Henares, 25 de junio de 2024