

Good manufacturing practices (GMP)

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Quality assurance system

The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. Operations shall be carried out in accordance with pre-established instructions and procedures. The system shall take account of the adequacy of personnel, their knowledge and skills, as is necessary to ensure that finished materials and articles comply with the rules applicable to them;

Quality monitoring system

The quality control system shall monitor the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP.

Documentation

The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article