
Annexes - Content

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Annex 1. Requirements for procedures and records in each respective GMP

The symbols at the margins in the chapters refer to the specific minimum requirement from the three different GMP texts. These requirements are shown here with referrals to their respective paragraph in the separate GMPs.

Procedures

EU GMP Guide Part I

- 1.3(i) Sampling etc of starting materials, intermediates and finished product
- 1.3(i) Monitoring environmental conditions
- 1.4 Regular reviews of corrective and preventive actions
- 2.2 Organisation chart
- 2.09 Training programme
- 2.13 Hygiene, health and clothing
- 3.2 Cleaning and disinfection
- 3.19 Storage temperature and humidity
- 3.36 Cleaning of equipment
- 3.41 Calibration and check
- 3.43 Sanitising of water systems
- 4.9 Data processing systems
- 4.11 Specifications for starting and primary or printed packaging materials
- 4.12 Specifications for intermediate and bulk products
- 4.13 Specifications for finished products
- 4.14 Manufacturing Formula
- 4.15 Processing Instructions
- 4.16 Packaging Instructions
- 4.19 Receipt of starting and primary and printed packaging material.
- 4.21 Internal labelling
- 4.22 Sampling
- 4.23 Testing materials and products
- 4.24 Release procedures
- 4.26 Validation
- 4.26 Equipment assembly and calibration
- 4.26 Maintenance, cleaning and sanitation
- 4.26 Personnel matters including training, clothing, hygiene
- 4.26 Environmental monitoring
- 4.26 Pest control

EU GMP Guide Part I (cont.)

- 4.26 Complaints
- 4.26 Recalls
- 4.26 Returns
- 4.27 Operating procedures for equipment
- 5.2 Handling of materials
- 5.19 Cleaning to avoid cross-contamination
- 5.20 Checking effectiveness of preventions
- 5.21 Validation
- 5.30 Identity of starting material
- 5.32 Dispensing
- 5.41 Issuing of printed materials
- 5.45 Line-clearance
- 5.49 Procedures for delayed labelling
- 5.57 Return of printed materials
- 5.62 Reprocessing
- 5.63 Recovery
- 5.65 Procedures for returned products
- 6.2 Duties of the QC department
- 6.7 Specifications
- 6.7 Sampling procedures (also 6.11)
- 6.7 Testing procedures (also. 6.15)
- 6.7 Calibration of instruments and maintenance of equipment
- 6.18 Process controls
- 6.19 Preparation of reagents and standards
- 6.21 Use of reagents
- 6.26 Stability programme
- 6.31 Agreement about stability studies by other party
- 7.1 Contract manufacture and analysis
- 8.2 Complaints
- 8.10 Recalls
- 9.1 Self inspections

EU GMP Guide Part II

- 1.2 Rationale for the point at which production begins
- 2.11 System for managing quality
- 2.14 Persons authorised to release intermediates and APIs
- 2.18 Notifying management of problems