

10. Surveillance Programme/Measures (used by firm and by regulatory authority)

- Sampling and audit procedures
- Recall monitoring (including effectiveness controls and verifications of procedures)
- Consumer complaint system/procedures
- Adverse reaction reporting system/procedures
- Drug product defect reporting system/procedures

11. Quality Management Systems

- Quality management/assurance system/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the GMP compliance programme, including establishment of standards and annual audit and review.