



QUALITY CONTROL
syllabus

Introduction to QC

- Introduction To Procedure of testing in QC.
- Introduction of QC Instrumentation.
- Introduction To QC documentation

Test Preform in QC

- **Description.**
- **Identification.**
- **Moisture content.**
- **Loss on drying.**
- **Assay.**
- **Dissolution.**
- **Content Uniformity.**
- **Related substances.**
- **Residual Solvents.**

Instrument used in QC

- Analytical Balance.
- UV Visible Spectrophotometry.
- Karfisher Auto Titration.
- Conductivity Meter.
- Polarimeter.
- Infrared spectro photo meter.
- Partical size Determination.
- Total Organic Carbon.

Instrument use in QC count.....

- Dissolution.
- Tablet Friabilator.
- Tablet Disintegration apparatus.
- High Performance Liquid Chromatography.
- Gas Chromatography.
- UPLC.

Instrument qualifications

- User Requirements Specification (URS)
- Design qualification (DQ)
- Factory Acceptance Testing (FAT)
- Site Acceptance Test (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ),

Calibration and Validation

- Calibration of Instrument
- Stability Chamber Validation
- Analytical Method Validation
- Analytical Method Transfer
- Analytical Method Development

Stability Study

- Stability study of drug substances.
- Stability study of drug Products.
- Stability study Planner Preparation.
- Sample Incubation.
- Stability sample analysis.
- Stability related deviations.

Quality Management Documents

- Deviation
- Incident
- Change Control
- OOS
- OOT investigation,
- CAPA
- RISK ASSESSMENTS

Documents Related to QC

- Protocol Writing
- Report Writing
- SOP Revision
- Specification Revision
- QC Data Review
- COA

Audit Related.....

- Data integrity
- 21 CFR
- ICH
- USP
- MHRA Guidelines
- Regulatory Audits and
- Internal Audits

Conclusion

- Conclusion of All Topics and
- Question Answer