

Course Outline

Topics include:

- QC regulation requirements
- Product sampling strategies
- Total protein quantitation and analyses (ELISA, Isoelectric Focusing, 2D gel electrophoresis, capillary electrophoresis, Western blot, HPLC)
- Endotoxin test
- QPCR to detect viral and mycoplasma contamination
- Water quality testing

On completion of this module, the student should be able to:

- Understand the basic functions of Quality Control entity in drug manufacturing facility
- Comprehend the various analytical methodologies in testing drug substances and products.
- Acquire competency in performance of the various relevant QC assay.