

Faculty of Pharmacy

Quality Control of Pharmaceuticals

Information:

Course Code: PT 010 Level: Undergraduate Course Hours: 3.00- Hours

Department: Pharm D

Description:

This course is designed to let the student have the necessary knowledge about the inter-relationship between quality control, quality assurance and good manufacturing practice as well as the concept of process validation (prospective, retrospective, concurrent and revalidation). In addition, the course covers quality by design, pharmaceutical regulations according to FDA & EMA (European medicine agency), ISO, BSI, and documentation. It will also cover the subjects related to good laboratory and analytical practice and sampling, including validation parameters for analytical methods according to ICH Guidelines Q2 R1, establishment of analytical methods of raw materials and end products, development of stability indicating assays, sampling methods and procedures.