

The Role of QC in the Pharmaceutical Industry



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QC Roles



- Evaluation of quality throughout process
 - Raw materials and API
 - Drug Product
 - Packaging components
 - Reassay
 - Retains

QC Responsibilities

- Efficacy
- Safety
- Quality
- Compliance
 - FDA, MHRA, ICH
 - USP, BP, EP, JP





Raw Materials

- All Raw Materials are tested on site before use
 - Incoming identity
 - Full release testing
- Includes Excipients, Capsules, API
- Various techniques
 - Raman and IR Spectroscopy
 - Assay (HPLC and Titration)
 - Physical Tests

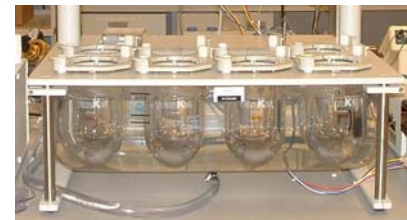
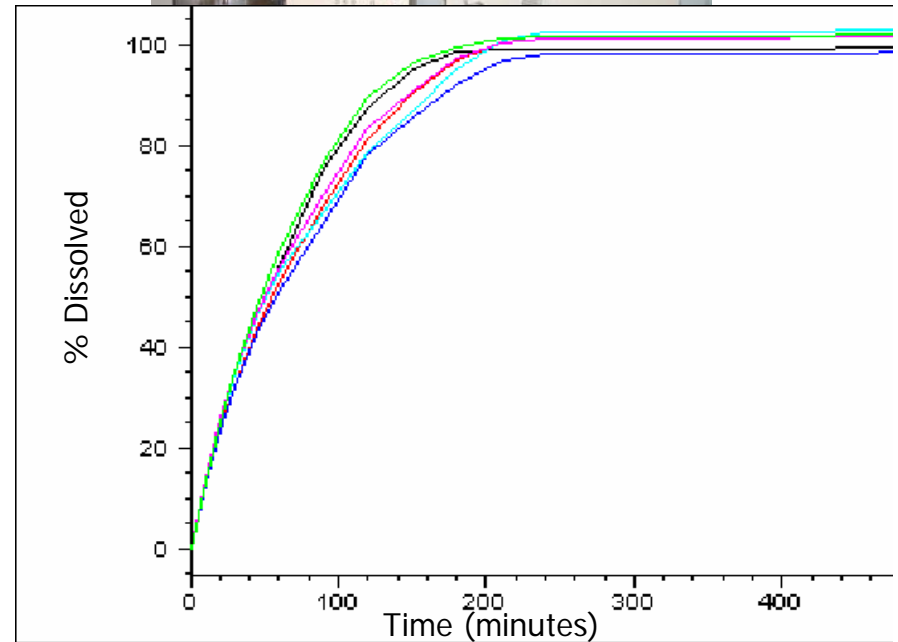
Packaging Components

- All packaging components tested if in contact with drug product
 - Bottles
 - Blister pack components
 - Cotton wool, Desiccants
- Range of techniques
 - Appearance
 - Spectroscopy
 - Loss on Drying



Finished Product (Release)

- Release into Clinic
- Mainly 2 techniques
 - HPLC
 - Dissolution
- Several tests
 - Assay
 - Content Uniformity
 - Dissolution





Finished Product (Reassay)

- Scheduled reassessment of released drugs
- Ensures continued efficacy
- Same techniques as Release
 - HPLC, Dissolution
 - Reduced testing for reassay
- Reassay schedule drug dependant
 - Comparators – manufacturers expiry
 - In house drugs – decided by formulator

Retains

- Sample of everything tested retained
 - Enough for full testing in duplicate
 - At label conditions
- Retain time determined by regulatory guidelines
 - Raw materials 12 Years
 - Finished products 10 Years
- All unsealed finished products inspected annually



Cleaning Verification

- All manufacturing equipment cleaned
- Subject Exposure Limit (SEL) set
- SEL converted to a Residue Limit (RL)
- Equipment swabbed
- Tested using HPLC
 - Std concentration made to RL
 - Swab concentration must be lower than std
- All surfaces must be validated



Future

- Process Analytical Technology
- Paperless laboratory
- Explore new uses of analytical techniques
 - NIR
 - IMS

