

Should Acceptable Product Yield be a Validation Requirement? Validation Case Study #6

May 11, 2013 11:07 am EDT

A validation case study involving a validated manufacturing process is described. The process met all acceptance criteria, and it was judged to be validated. Products from the manufacturing process had a significant level of waste and rejects. Eventually, the defect level became so high that business people intervened and requested investigation. The problem was caused by a major excipient with significantly different particle size distribution obtained from a new supplier. US Food and Drug Administration good manufacturing practice (GMP) regarding yield requires that product be formulated...

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