

# **Specification Of Drug Substances And Products: Development And Validation Of Analytical Methods By Thomas W. Rosanske;Shelley R. Rabel Riley**

**By Thomas W. Rosanske;Shelley R. Rabel Riley**

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development and validation of analytical methods. [Christopher M Riley; Thomas W Rosanske; Shelley R Rabel Riley;] # Drug development schema:

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Who Should Attend? This course is intended for those who want to improve their understanding of the overall process of developing specifications for drug substance

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The Food and Drug Administration (FDA) is publishing a guidance entitled ``Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New

Water content / LOD : 6 Water content / LOD Water content ( % w/w or w/v) This test is important in cases where the new drug substance is known to be hygroscopic or

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