

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: Specification of Drug Substances and Products . Christopher M. Riley, Thomas W. Rosanske, Shelley R. Rabel

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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

for the purposes of the drug substance specification, Profiling and qualification of drug substance impurities and drug product degradants are typically

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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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finalization of the Guidance for Industry Stability Testing of Existing Drug Substances and Products in New Drug Products Q6A Specifications:

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Acceptance Criteria for New Drug Substances specifications applies to drug products only; zit
pertains to the establishment of more restrictive criteria for the