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Development And Validation Of Analytical Methods
By Thomas W. Rosanske;Shelley R. Rabel Riley**

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Guidance 18: Impurities in drug substances and drug products 18.1 Impurities in drug 18.2 Related impurities in drug substances and drug products

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Required API and Drug Product Specifications . Proper foundation for specification
assignments;
<http://www.cfpie.com/agenda.aspx?productid=011>

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only; zit pertains to the establishment of more restrictive criteria for the
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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
<http://www.authorstream.com/Presentation/snagabiru-1405285-specifications-drug-substances/>

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