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Analytical profiles of drug substances. Compiled under the auspices of the Pharmaceutical Analysis and Control Section, Academy of Pharmaceutical Sciences. Includes bibliographical references and indexes. 1. Drugs--Analysis. I. Florey, Klaus. 11. Brewer, Glenn A. Pharmaceutical Analysis and Control Section. [DNLM: 1. Drugs--Analysis--Yearbooks.

Analytical Profiles of Drug Substances. Volume 13

Analytical Profiles of Drug Substances and Excipients Published: 26th November 2002 Editor: Harry Brittain Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or ...

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be established in the form of an Analytical Target Profile (ATP), which contains the desired performance criteria for the measurement of the attribute(s), eg, impurities, API content, potency, etc. The ATP defines the appropriate performance criteria for the analytical result and is method-independent.

Table 5: Scope of Analytical Target Profiles (ATP) in

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Analytical Profiles of Drug Substances and Excipients

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