

What is the difference between related compounds and related substances in pharmaceutical HPLC – FAQ

Related compounds are composed of all process-related substances that are related to the main compound of interest.

This can include degradants that may be formed in the formula. By definition, any component of a drug substance that is not the chemical entity defined as the drug substance and in addition, for a drug product, any component that is not a formulation ingredient. Impurities are classified by the USP as Organic impurities (process- and drug-related), Inorganic impurities, Residual solvents.

Related substances are structurally related to a drug substance.

These substances may be identified or unidentified impurities arising from the synthesis manufacturing process, such as starting materials, intermediates, or by-products, and do not increase on storage, or identified or unidentified degradation products that result from drug substance or drug product manufacturing processes or arise during storage of a material.

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MicroSolv Technology Corporation

9158 Industrial Blvd. NE, Leland, NC 28451

tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com

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