

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.