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Pharmaceutical Product-related Substance

National Cancer Institute

Source

National Cancer Institute. *Pharmaceutical Product-related Substance*. NCI Thesaurus. Code C42666.

Molecular variants of the desired biological product formed during manufacture and/or storage, which are active and have no deleterious effect on the safety and efficacy of the drug substance or drug product. These variants possess properties comparable to the desired product and are not considered impurities.