

Difference between assay and purity regarding pharmaceutical analysis - Primer

DATE: 30-DECEMBER-2012 Last Updated: 16-JUNE-2025

If you're new to HPLC or pharmaceutical testing, you might wonder: what's the difference between an assay and a purity test? While they sound similar, they serve different purposes in quality control.

What Is an Assay?

An assay measures the **amount or potency** of the main active ingredient (called the *analyte*) in a pharmaceutical product. Think of it as answering the question:

"How much of the drug is actually in this tablet or solution?"

Assays are used to confirm that the product contains the correct dosage of the active substance, as stated on the label.

What Is a Purity Test?

A purity test, on the other hand, focuses on **what else is in the sample**—specifically, **impurities**. These can include:

- Related substances (chemically similar compounds)
- Residual solvents (leftover from manufacturing)
- Degradation products (formed over time)

Purity testing ensures that these unwanted substances are present only in very small, acceptable amounts.

Why It Matters

Both tests are essential for ensuring *drug safety and effectiveness*. While the assay confirms the drug delivers the right dose, the purity test ensures it doesn't contain harmful or excessive impurities.

Want to Learn More?

For more detailed guidance, refer to the International Council for Harmonisation (ICH) guidelines, especially:

- **ICH Q2(R2)** – Validation of Analytical Procedures
- **ICH Q3A/B** – Impurities in New Drug Substances and Products

Printed from the Chrom Resource Center
Copyright 2025, All Rights Apply
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