

Some of the following parameters must be considered to have a validated HPLC method for use with SOP, GMP, GLP and other pharmaceutical, environmental and forensic applications:

Accuracy: How close the observed value is to the true value. This is analogous to an archer hitting the “intended” point each time he shoots his arrow. If the center is hit, it is accurate. It is unrelated to **Precision**.

Chiral HPLC: A variation of classic column chromatography where the stationary phase contains a chiral selector. Enantiomers and racemates will have different retention and affinity to the chiral selectors. Chiral selectors range from oligosaccharides, cyclodextrins, amino acids & antibiotics.

Detection Limit: The lowest reliable, detectable amount of your **analyte** is considered the **detection limit** of your method.

Glycoside: A **glycoside** is any molecule in which a sugar group is bonded through its anomeric carbon to another group via an O-glycosidic bond or an S-glycosidic bond; glycosides involving the latter are also called thioglycosides.

Linearity: If the raw data (actual results without any correction) of your run is proportional to the concentration of your **analyte** of interest (within the established range of testing), your method will be considered linear.

Nucleoside: Many of various compounds consisting of a sugar such as ribose or deoxyribose and a **purine** or **pyrimidine** base, especially a compound obtained by hydrolysis of a nucleic acid such as adenosine or guanine. A **glycoside**.

Nucleotide: Any of various compounds consisting of a **nucleoside** combined with a phosphate group (phosphoric ester) and forming the basic building block of DNA or RNA.

purine

Purine: A heterocyclic aromatic organic compound consisting of a **pyrimidine** ring fused to an imidazole ring.

Precision: How “tight” the observed values are relative to each other that is independent of personnel, time and instrumentation; and without any intervention in the method. **Precision** is analogous to an archer hitting the same place each time on a target. It can be very far off the center, but it is still precise if he is hitting the same point each time.

pyrimidine

Pyrimidine: a heterocyclic aromatic organic compound similar to benzene and pyridine and, containing two nitrogen atoms at positions 1 and 3 of the six-member ring. It is isomeric with two other forms of diazine. Uracil is an example.

Quantitation Limit: This is closely related to **Detection limit**. The lowest amount of your **analyte** that can be reliably quantified is considered the **quantitation limit** of your method.

Recovery: This is the amount of your **analyte** that is detected during your method.

Repeatability: This is very closely related to **Precision**. This takes into account your sample. A method can be considered repeatable when, from a homogeneous sample, **Precision** is achieved.

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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

Reproducibility: This is closely related to **Precision**. A method will be considered Reproducible when **Precision** can be achieved in separate methods and independent of location and time and operator of the method.

Robustness: When variations of the analytical conditions do not change the reliability of your data no matter how small the variations are then your method is considered Robust.

Specificity: How well a species is separated from or resolved from interferences in the actual run.

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