# Summary - Process Validation Sampling for Non-Sterile Liquid / Semi-Solid Drug Products

This guidance provides Process Validation Sampling guidelines for non-sterile liquid (solutions and suspensions) and semi-solid (ointments, creams, pastes, gels and lotions) drug product dosage forms.

Sampling of solutions pose few special concerns as all materials are in solution and each sample is the same as every other sample if homogenous.

For solutions the key aspects that should be addressed during validation include assurance that the drug substance and preservatives are dissolved and that the solution has been adequately mixed.

Ointments, Creams, Pastes, Gels and Lotions are often prone to separation or settling and may pose special concerns for sampling.

In formulations where the active pharmaceutical ingredient (API) is soluble in the base or vehicle, API uniformity would be expected to present less of a problem than those formulations where the API is insoluble and is suspended, as may be the case with certain semi-solid dosage forms. In the latter case, API uniformity would depend upon control of particle size, and the use of a validated mixing process.

A concern is mixer design and the presence of "dead spots" where quantities of the formula are stationary and not subject to mixing. Sampling points should include these points as part of the sampling plan.

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