

Guidance Number: 125

Table 1 – Validation Criteria for Solvent Processes

Type of Solvent (Recovered or Recycled)	Reuse of Solvent	Validation of Solvent Recovery or Recycle Process and Equipment Required?	Test Requirements
Recycled or Recovered	Returning solvent to parent process step. Recycle of solvent phases or distillates as an integral part of the production process.	No	Suitable for intended use and meets any regulatory specifications (RS). May be less than virgin specifications if supported by approved scientific rationale or data. Recycled distillates must be characterized for degradants and/or impurities. Characterization must span the timeline over which the recycled solvent will be used, or an adequate purge rate of degradants and/or impurities must be demonstrated.
Off-line Recovery	<ul style="list-style-type: none"> Returning solvent to earlier or later steps of the same product; Use of solvent for equipment cleaning for a different API than the one from which the solvent is recovered, but excluding final rinse of equipment; or Use of solvent for equipment cleaning for the same API from which the solvent is recovered, including the final rinse. 	No	Suitable for intended use and meets any regulatory specifications (RS). May be less than virgin specifications if supported by approved scientific rationale or data.
Off-line Recovery	Use of recovered solvent for final cleaning rinse test for a different API than the one from which the solvent is recovered.	Yes	Suitable for intended use and meets any regulatory specifications (RS). Must meet most stringent specifications for all intended uses, including volatile and non-volatile impurities.

Type of Solvent (Recovered or Recycled)	Reuse of Solvent	Validation of Solvent Recovery or Recycle Process and Equipment Required?	Test Requirements
Off-line Recovery	Use of recovered solvent from step of one process into any step of any other.	Yes	Test to most stringent specifications for all intended uses, including volatile and non-volatile impurities