

Summary - Use and Recovery of Solvents in API Manufacturing

Prerequisites for Solvent Recovery Process Validation include, and are not limited to, the following:

- Approved production Instruction-Records and applicable SOPs;
- Identification of all solvent recovery Critical Process Parameters;
- Qualification of direct impact equipment, facilities and systems, (including computerized systems). Verification of completion of equipment qualification should be included in the validation protocol; exceptions to this requirement should be approved by the Validation Committee (VC);
- Approved specifications for finished recovered solvent product and in-process testing;
- Validated test methods used to demonstrate quality requirements; and
- Personnel taking part in the validation work should be trained and qualified before carrying out such work, with training records documented.

Validated Solvent Recovery Processes that undergo major changes to incoming used solvent streams (e.g., those requiring a new solvent recovery process, or a stream that does not fit established criteria) require revalidation. In addition, major changes to equipment, facility, procedures or the solvent recovery process may require revalidation. Minor changes may not require revalidation but may require a documented, expanded test program or other formal evaluation.

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