

Guidance Number: 010

Figure 1: Types and examples of product grouping

Cleaning for the same chemical entity. Cleaning for drug product formulations with same API(s).	Crude and Pure for the same API. Validation runs for either step may be equivalent. Formulations within a drug product family, such as different strengths or similar base formulations.
Cleaning with the same cleaning instructions	Products A, B and C are cleaned using the same procedure. If B is the worst case and its' cleaning procedure is successfully validated, then A and C would also be considered validated.
Products cleaned manually using the same procedure	Several products using essentially identical equipment (e.g., reactors, centrifuges, blenders, granulators, mills, tablet presses) and cleaned using the same procedure. This procedure typically includes dismantling to clean, and visual inspection

Figure 1: Types and examples of equipment grouping

Types and examples of equipment grouping include:

Identical Equipment (Grouped by type and similar or identical utilities and accessories)	Reactors (vessels with heating, cooling and a condenser); Receivers (tanks with no heating, with or without agitation) cleaned by an individual procedure. Blenders or Mixers (same configurations/accessories with respect to cleaning). Tablet Presses (same cleaning procedures/accessories/parameters)
Grouped by gross function	Where one individual cleaning procedure is used for all product cleanups (e.g., Centrifuges and dryers, or Fitzmills and Comils, Granulators). This applies where there is mostly manual disassembly.
Grouping Minor Equipment	For example, scoops, shovels, filter plates, filter housings, spatulas. Relatively small equipment that is manually cleaned and has no moving parts can usually be cleaned by the same procedure.