• Agitation
• The extent of manual intervention required to produce expected results

**Product Grouping**
For the purpose of cleaning validation a group of related products to be identified and a single product selected as 'worst-case' or representative of the product family The rationale for the grouping must be documented. Types and examples of product grouping include:

**Figure 1: Types and examples of product grouping**

Once products are appropriately grouped, the worst-case product or products can be selected from among the group for the purpose of executing the cleaning validation protocol. A number of scenarios are possible:

- Within a group, two or more products may be determined to provide an equivalent 'worst-case' challenge to the cleaning procedure. Once the rationale for equivalency has been documented and approved by the Quality Authority, the equivalent products are used to demonstrate the effectiveness of the cleaning procedure during validation.
- Example: Product A and Product C are established as equivalent worst-case challenge products for the cleaning procedure used for products A, B, C, D and E.

During validation, any lot combination of Products A and C are used to fulfill the 3 validation cleanup requirement (e.g. 3 of A **or** C, 2 of A and 1 of C **or**1 of A and 2 of C).

- Within a group, two or more products are determined to be 'worst-case' challenges, but are not equivalent. Each worst-case product should be subjected to the 3 validation cleanup requirement.

- The same cleaning procedure is used for two or more groups of products. Each worst-case product within each group should be subjected to the 3 validation cleanup requirement, unless a rationale is documented and approved by the Quality Authority that the worst-case product of one particular group is clearly a worst-case product for all groups.

- Other scenarios may be possible and each product, or any new product introduced to the site, should be evaluated on a case-by-case basis.

The criteria that should be considered when selecting a worst-case product or products include:

- Solubility of the residues in the cleaning agent, including cleaning and rinse solvents - the least soluble residue among a group is the most common approach.

- Ease of removal by a detergent, if applicable.