

Standard Operating Procedure

Title: Procedure for Cleaning Validation

3. Worst-case product is the same as previously validated and acceptance criteria is the same or higher than previously validated.
4. Cleaning validation data is available on the previously validated identical process.

An explanation for reduced testing should be described in the relevant Validation Plan, protocol or change request for the process. Reduced testing may include reducing the number of tests and reducing the sample locations to a few key critical areas known to be "critical sites" or "hot spots".

For changes to current cleaning processes and procedures the extent of retesting will in most cases be reduced to a single test, this shall be stated and approved as part of the change request process as in SOP QMS-030.

3.3. Select Worst-Case Product for Cleaning

For multi-product equipment it is not practical to validate cleaning of all products produced in a particular process/equipment that has one cleaning process and where products are alike in formulation and dosage form. In such cases, it is considered acceptable to select a worst-case product to represent all products in the process for the purposes of cleaning validation. The worst-case selection is based on a scientific justification i.e. the least soluble product produced on a particular equipment or process. This product is then used to validate cleaning for that process/equipment.

3.4. Select Product to use for acceptance criteria calculations

1. Calculation of acceptance criteria is to be based on the most toxic product within a group of products produced in a given process.
2. Find the product within the product group, which has the lowest active toxicity value in mg/kg, this is the most toxic product. This product will be used for the calculation of acceptance criteria.

3.4.1. Example of selecting worst-case product and product for acceptance criteria calculations

Note - a low toxicity value means high toxicity, a high value means low toxicity.

Active	Active solubility in water (mg/mL)	Active Toxicity (mg/kg)
1	60	90
2	400	2800
3	70	0.30

From the above table of product data, Active 1 is the least soluble product in water since it has a value of 60 mg/mL and is therefore the worst-case product in this group.

Active 3 is the most toxic product since it has the lowest toxicity value of 0.3 mg/kg. Therefore the acceptance criteria is calculated using active 3 product data.

3.4.2. New Products Introduced to the Production Facility

If a new product is introduced into the facility the solubility and toxicity of the new product should be compared against the current list of products in the same product type group and following assessment should be made:

- If the new product is less soluble than the current least soluble product within the product group then this product becomes the new worst-case