

- If a specific method is being validated, then specificity studies need to be performed for the analyte of interest. The potential for interference from the following should be considered:
 - Swab extractables
 - Cleaning agents
 - Sample containers and lids
 - Excipients and other compounds potential present
- If a specific method is being validated for a cleaning agent, the only specificity experiment typically executed is specificity from swab extractables.

Range

The equipment cleaning analytical method should be validated around the calculated RAL for the material. The method is considered valid for any RAL within the validated recovery range. If the RAL falls outside the validated recovery range, the method should be revalidated with respect to the affected elements (e.g. range, linearity).

Linearity

Linearity should at a minimum cover the expected analyte RAL and encompass the levels included in repeatability and recovery studies. The lower end of the linearity study shall take into consideration the correction factor for sampling recovery, if applicable (e.g. if the RALs have a range of 4-6 ug/cm² and the recovery is 50 percent, the linearity study should include levels of 2-6 ug/cm²).

Intermediate Precision

Intermediate precision is the study of the effects of random events (e.g. days, analysts, equipment etc.) on the precision of the analytical procedure. A method intermediate precision experiment should be conducted unless there is a documented rationale otherwise (e.g. a reliable and robust swabbing verification program is implemented). Method intermediate precision should include use of a second Lab Analyst, on a different day, using different solutions and different analytical equipment, if possible.

System Suitability

System suitability should be conducted for systems such as HPLC and TOC. Although non-specific methods like UV, pH etc. may be used; the ability of the selected method to detect the residue shall be demonstrated (for example UV absorbance at the residue maximum wavelength and non-interference of the rinse solution).

Recovery Studies

Analyte residue recovery shall be challenged as part of the analytical method validation. The recoveries of each material (product or cleaning agent) from the different process-contact surfaces that constitute the major portions of equipment's surface area are typically demonstrated. Alternatively, the recovery value of a worst case material could be substituted for all the materials sampled with the same rinse solvent. Typical surfaces may include hastelloy, stainless steel, glass/glass lined carbon steel and PTFE (polytetrafluoroethylene).

The solvent used in the recovery study should be the same as is used for routine sampling.