

Guidance 014 Cleaning Evaluation Documentation and Records for Cleaning Activities

- If a grouping strategy will be used, document that the design of equipment, and/or the characteristics of the products are sufficiently similar to scientifically justify the grouping rationale.
- If the cleaning evaluation is to address more than one active ingredient or API step, then justification for the scope should be included as well as the rationale for the selection of worst case materials if the process is to be validated.
- Consideration of removal requirements for microbiological organisms and cleaning agents (if used), including any non-active containing drug product materials such as granulating or film-coating solutions. A documented and approved risk assessment should be performed to determine if microbial acceptability limits are required for cleaning validation of non-sterile product contact equipment and considerations.

Any documentation used to describe and justify the cleaning validation approach should be subject to site change control procedures and be reviewed and approved by the site Quality Authority and Production Authority.

Figure1: Guidance on item to be considered as part of the cleaning evaluation is given in the following table.

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Item No.	Items to be considered in the Cleaning Evaluation	Include consideration/justification for:
1.	Material to be cleaned	<ul style="list-style-type: none"> ● Process Intermediates ● APIs ● Raw Materials (including processing aids, catalysts) ● In-process Materials and Drug Products ● Cleaning and sanitizing agents ● Solvents ● Bacterial Endotoxins, when applicable ● Microorganisms, when applicable

- **Severity** of impact
Based on toxicity / minimum therapeutic dose

Cleaning Instruction-Records

Equipment Cleaning Instruction-Records should be written in a detailed stepwise format for manual cleaning methods and in a defined sequential operation for automated cleaning systems.

Completion of each significant cleaning cycle should be recorded either manually (initial, date, and time) or using a validated computerized system.

Such instruction-records should include or reference, at least, the following parameters, where applicable:

- Cleaning and sanitizing agents, including concentration, amount to be used and contact time;
- Quality of water or other solvents used;
- Requirements for equipment disassembly and re-assembly;
- Temperature and pressure parameters;
- Flow rates or times of known volumes for wash solutions and rinses;
- Identification of defined recycle and transfer piping pathways for cleaning;
- Start and end times of each critical cleaning cycle or step;
- Volume or weight of rinse;
- Number of rinses;
- Frequency of cleaning (e.g., Campaign length or after each batch);;
- Tools and/or utensils employed;
- Agitation, recirculation, and/or reflux;
- Draining and drying;
- Identification and inspection of dead-legs;
- Method for indicating equipment cleaning status;
- Method for protecting clean equipment from contamination;
- Maximum time intervals for between use and cleaning; and
- Verification of critical cleaning steps and supporting data (e.g., UV, pH, visual inspection).

Cleaning Solutions that are prepared and stored should be prepared following written instructions-records and labelled to indicate, at least, the following information:

- Signature or initials of person preparing the solution;
- Concentration of solution at time of preparation;