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| **Validation Study -Summary** | |
| Title | *Define your study* |
| Introduction | *Explain the reason and the background why this validation should be done, and the hazards that need to be managed* |
| Objective | *To pass the acceptance criteria* |
| Factory |  |
| Validation or Revalidation | *Indicate if this study is a validation for new installation or a revalidation due to change* |
| Validation/Revalida-tion date | *The date that validation/revalidation study completed* |
| Scope | *Description of the process or part of the process that shall be validated/revalidated (cluster processing groups where possible)* |
| Products | *Indicate which product you choose and reason (products can be grouped, and worst-case product should be chosen)* |
| Number of repeats | *Describe the number of successful validation/revalidation repeats based on the outcome of the risk assessment (see 5.1.1)* |
| Results | *Pass or Fail?* |

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| **Validation Team** | | | | | |
|  | Team Leader | Member | Member | Member | Member |
| Name |  |  |  |  |  |
| Responsibility |  |  |  |  |  |

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| **Validation Approval** | |
| Name |  |
| Job Title |  |
| Date |  |
| Signature |  |

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| **Referenced Documentation and Their Review for Qualification (see 5.1)** **(If need, documents can be attached in appendix)** | | | |
| **Validation Input Requirements** | **Name and Issue Date** | **Qualification (Yes/No.) and Date** | **Remarks** |
| Qualified Process (Doc. 34)\* | *List relevant P&ID’s with names and issue dates* | *List dates of qualification* |  |
| Assessment of Process Equipment (legacy equipment) | *List relevant P&ID’s/documents with names and issue dates* | *List dates of assessment* | If no assessment data is available, a new assessment needs to be included.  List issues identified and *e.g.* if further dismantling is required |
| Qualified CIP Installation (Doc. 50 Annex C) \* | *List relevant P&ID’s with names and issue dates* | *List dates of qualification* |  |
| Standard Operating Procedures (SOP) for the cleaning (and disinfection, if applicable) | *List relevant SOPs with names and issue dates* | *List dates of review* |  |
| Calibration records | *Check if calibration is valid for all relevant equipment* | *The last calibration date* |  |
| Maintenance records | *Check if maintenance is done according to schedule* | *Yes/No* |  |
| Analytical data of water quality (e.g. hardness, micro data, pH *etc*.) | *Check if all analytic data are according to specifications* | *Yes/No* |  |
| Specifications of the chemicals used | *Check if cleaning chemicals compliant with equipment specification and suitable for the application* | *Yes/No* |  |
| Cleaning training records of staff | *Check the training records of staff performing cleaning operations* |  |  |
| For revalidations: historical data of monitoring and verification activities (out-of-limits situations and the completion of corrective actions). |  |  |  |

*\*: If qualification evidence is not available, an evaluation should be performed to determine if and how the cleaning validation can proceed, e.g. carry out corrective action and identify critical sampling points.*

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| **Worst Case Scenario** **(see 5.1.2)** | |
| Identified Difficult to Clean Areas | *List and describe the most difficult areas to clean (e.g. photographs, or drawing, spray shadow test results)* |
| Product | *In line with 5.1.2* |
| Soiling condition | *Related to selected products, process conditions, locations and soil loading* |
| Cleaning parameters | *least optimal temperature, cleaning agent concentration, time or flow* |
| Other relevant parameters |  |

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| **Scope of Validation Study** | | |
| CIP Unit | Object to be cleaned | Circuit/Loop |
| Identification of CIP unit | List name of equipment | List here or indicate in P&ID about each segment of solution pipelines, product pipelines, and process equipment which are cleaned during an individual CIP cycle |
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| **Report of Production Cycle** | |
| Product |  |
| Length of Production |  |
| Deviations or other events |  |

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| **Water Quality** | | | |
| Hardness |  | | |
| Microbiological data |  |  |  |
| pH |  |  |  |
| Conductivity |  |  |  |

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| **Cleaning Types** | | |
| Cleaning Programme | Yes/No | Yes/No |
| Change-over cleaning |  |  |
| Midshift/Inter-mediate Cleaning |  |  |
| End of production |  |  |
| Deep cleaning |  |  |

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| **ClP verification: Cleaning Parameters** | | | | | |
| Stage | Parameter | Set Point | Validation 1 <Date> | Validation 2 <Date> | Validation 3 <Date> |
| Pre Rinse | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Detergent - <Product Name> | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Conductivity |  |  |  |  |
| Intermediate Rinse | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Acid Cycle - <Product Name> | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Conductivity |  |  |  |  |
| Final Rinse | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Conductivity |  |  |  |  |
| Disinfection - <Product Name> | Time |  |  |  |  |
| Temperature |  |  |  |  |
| Supply Flow Rate |  |  |  |  |
| Return Flow Rate |  |  |  |  |
| Pressure (bar) |  |  |  |  |
| Conductivity |  |  |  |  |
| Remark: | | Start Time |  |  |  |
|  | | End Time |  |  |  |
|  | | Total Time |  |  |  |
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| **Relevant Contaminant, Sampling Plan, Test methods and Acceptance Criteria: **(See 5.1.3, 5.1.4 and Annex B)**** | | | | |
| *Remark: It is not recommended to conduct any analytical sampling and testing if the area is not visual clean* | | | | |
| Surfaces Sample Location and Name | Contaminant | Size of Sampling Area | Test Method | Acceptance Criteria |
| 1. Manhole sealing of Tank A | Product residue | Total | Inspection with the help of torch/flashlight, UV lamp, Inspection mirror etc. Photo | Visually clean without residues |
| Microbes | ATP | Swab and ATP test | ≤ xx RLU |
| Total viable count (TVC) | 10x10 cm | Swab and TVC analysis | ≤ 100 cfu / 100 cm2 |
| 1. Sieve before supply pump | Product residue or particles | Total | Visual inspection, Photo | Visually clean / free of particles |
| Microbes | ATP | Swab and ATP test | ≤ xx RLU |
| Total viable count (TVC) | 10x10 cm | Swab and TVC analysis | ≤ 100 cfu / 100 cm2 |
| 1. Shaft of stirrers | Product residue | Total | Inspection with the help of light (UV or flashlight)  Photo | Visually without residues |
| 1. Tank bottom | Residue | Total | Inspection with the help of light (UV or flashlight)  Photo | Visually clean without residues |
| Residue | Total | Spray shadow test | Visually clean, absence of UV light reflection |
| Total viable count (TVC) | 10x10 cm | Swab and TVC analysis | ≤ 100 cfu / 100 cm2 |
| Enterobacteriaceae/ coliforms | 10x10 cm | Swab and microbiological analysis | n.d. |
| Chemical residue (by pH) | 10 cm | pH Test stripes | 6-8 |
| PAA residue | 10 cm | PAA Test stripes | ≤ 5 ppm |
| Protein | 10x10 cm | Clean Card | ≤50 µg/100 cm² |
| Odor |  | Olfactory investigation | Odour unremarkable |
| 1. Sampling valve | Visual clean | total | Inspection with auxiliary light (UV or flashlight)  Photo | visually without residues |
| Protein | 10x10 cm | Clean Card | ≤ 50 µg/100 cm² |
| Total viable count (TVC) | 10x10 cm | Swab and TVC analysis | Swab and TVC analysis |
| Enterobacteriaceae/ coliforms | 10x10 cm | Swab and microbiological analysis | n.d. |
| … | … | … | … | … |
| Rinse Water/Product Testing | Contaminant | Size of Sampling Area | Test Method | Acceptance Criteria |
| Location xx  (e.g. CIP return 1) | Chemical residue | … ml | Surface tension test e.g. Camphor test | Rotation crystals |
|  | Chemical residue (by pH) | … ml | pH Test stripes | 6-8 |
|  | Product residue | … ml | Visual inspection | No particle, clear colourless |
|  | organic residue (by COD) | … ml | Photometry | ≤ 15 mgO2/L |
|  | Total viable count (TVC) | … ml | TVC analysis | TVC ≤ 100 cfu/ml |
|  | Enterobacteriaceae/ coliforms | … ml | Positive/negative-control with lactose-Peptone Bouillon | n.d. in 100 ml |
|  | … | … ml | … | … |

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| **Photos of Surface Sample after Cleaning** | | | | | | | |
| *Remark: Photos as example of successful cleaning* | | | | | | | |
| Sample 1  Location 1: e.g. Manhole sealing of Tank A | | | | Sample 2  Location 2: | | | |
| <Photo> | | | | <Photo> | | | |
| Sample 3  Location 3: | | | | Sample 4  Location 4: | | | |
| <Photo> | | | | <Photo> | | | |
| Sample 5  Location 5: | | | | | Sample 6  Location 6: | | |
| <Photo> | | | | | <Photo> | | |
| **Surface Sample** | | | | | | | |
| ***Note:*** *After “opening” the system was then cleaned and disinfected again.* | | | | | | | |
| Sample Location | Method | Acceptance Criteria | Validation 1  <date> | | | Validation 2  <date> | Validation 3 <date> |
| 1 | Visual inspection | Visual clean |  | | |  |  |
| ATP | ….. |  | | |  |  |
| TVC | …... |  | | |  |  |
| … | … |  |  | | |  |  |
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| **Visual Inspection Results (photos)** | | |
| Validation 1 <Date> | Validation 2 <Date> | Validation 3 <Date> |
| Sample 1: <Location> | | |
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| Sample 2: <Location> | | |
| **Sample 2: <Location>** |  |  |
| Sample 3: <Location> |  |  |
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| **Rinse Water/Product Test** | | | | | |
| Sample Location | Method | Acceptance Criteria | Validation 1  <date> | Validation 2  <date> | Validation 3  <date> |
| Rinse water 1 | pH | 6-8 |  |  |  |
| TVC | ≤ …cfu/ml |  |  |  |
| Enterobacteriaceae | ≤ …cfu/g |  |  |  |
| Rinse water 2 | … |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Final product | TVC | ≤ …cfu/g |  |  |  |
| Entero | n.d. |  |  |  |
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| **List of Corrective Actions (if applicable)** |
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| **Validation Comments (Observations, deviations, etc.)** |
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**Appendix:**

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| **Analytical Methods / Devices :** | | |
| Method | SOP/Device | Remark |
| *Visual inspection* | *UV light* |  |
| *TVC* | *SOP xxx* |  |
| *Enterobacteriaceae/ coliforms* | *SOP xxx* |  |
| *Protein:* | *SOP* |  |
| *Peracetic acid:* | *Test strip of ……* |  |
| *Allergen* | *Lab xxxx* | *Certification….* |
| *……….* |  |  |

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| **Reference Documents Attachment** |
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