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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 1Location 1: e.g. Manhole sealing of Tank A | Sample 2Location 2:  |
| <Photo> | <Photo> |
| Sample 3Location 3:  | Sample 4Location 4:  |
| <Photo> | <Photo> |
| Sample 5Location 5:  | Sample 6Location 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> |
|  |  |  |
| 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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