

SFE PROCESS EQUIPMENTS ARE GMP COMPLIANT

| Items | Standard | GMP |
|-------------------------|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Pumps | Piston | Piston with material certificate for all parts in contact with CO2 + FDA certificates for seals |
| Parts | Material certificates just for high pressure vessel | Material certificates for all parts |
| | Standard surface roughness | Surface roughness control |
| | No engravement of material traceability on parts | Material traceability engraved on each part |
| Skid | Aluminium or standard stainless steel | Aluminium or standard stainless steel To be easily cleaned |
| Vessel | Top lid screwed | Top lid screwed |
| | Standard finish | Surface roughness control |
| Vessel heaters | Electrical + Flexible insulation jacket | Electrical + Flexible insulation jacket + Stainless Steel cover |
| Seal | No FDA required | FDA approved with material certificates |
| PLC / Control | Batch or any kind of loading | Batch N° or Lot N° recorded: mandatory (already included into the standard program) |
| | No specific safeties on data logging | UHH safety parameters recording (already included into the standard program) |
| | No specific validation of recipes / parameters Any changes can be done at any time | Specific validation of the recipes / parameters Changes to be validated |
| Documentation / Quality | Specifications for pressure vessel only | Specification for pressure vessel and all items |
| | Basic electrical tests | Site Acceptance Tests procedure to be validated before tests Each parameter recorded Data report |
| | Basic automation tests | Site Acceptance Tests procedure to be validated before tests Each parameter recorded Data report |
| | Basic process tests | Site Acceptance Tests procedure to be validated before tests Each parameter recorded Data report |

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|----------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| | Electrical wiring control | Electrical wiring control Data report |
| | Operators training on the program / Machine operation / Maintenance | Operators training on the program / Machine operation / Maintenance Qualification / Certification to be obtained before operation |
| | Extraction process for equipment validation | Site Acceptance Tests procedure to be validated before tests Each parameter recorded Data report |
| | No specific operation qualification | Qualification / Validation of the process and operation Data report |
| General design | No dead volume | No dead volume |
| | All parts of the machine to be flushed | All parts of the machine to be flushed |
| | Standard cleaning procedure | Specific cleaning procedure with quality control of the cleaning product at the outlet |
| General project management | Functional analysis of the process | Functional analysis of the process |
| | No specific requirements | HAZOP studies (to be done by customer + SFE Process involvement) |
| | Standard HSE management | Dedicated Health / Safety / Environment management and studies |
| | Standard Sub-contractor validation | Dedicated Sub-contractor validation |
| | Standard Design / Manufacturing / Assembly validation steps | Dedicated and detailed Design / Manufacturing / Assembly validation steps |