PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# FAILURE MODE EFFECT ANALYSIS FOR VIBRO SIFTER

| PREPARED BY | | |
|---|---|---|
| **NAME** | **DESIGNATION** | **SIGNATURE / DATE** |
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| CHECKED BY | | |
|---|---|---|
| **NAME** | **DESIGNATION** | **SIGNATURE / DATE** |
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| APPROVED BY | | |
|---|---|---|
| **NAME** | **DESIGNATION** | **SIGNATURE / DATE** |
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| Revision | Date | Reason for revision |
|---|---|---|
| 00 | | First issue |
| | | |
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# FAILURE MODE EFFECT ANALYSIS FOR VIBRO SIFTER

| S. No. | Document Title | Document Number |
|---|---|---|
| 1. | Validation master plan | |
| 2. | Project validation plan | |

| Name (block letters) | Function | Signature |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

# FAILURE MODE EFFECT ANALYSIS FOR VIBRO SIFTER

| Level | Descriptor | Example detail description |
|---|---|---|
| | | • Minor effect on personnel health<br>• Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output.<br>• Effect on environment such as clean room. |
| 3 | Major | • Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc.<br>• Failure could lead to regulatory non-compliance.<br>• Loss/ damage to equipment or its critical sub-components<br>• Critical instruments not calibrated or not of desired range or accuracy.<br>• Proper supporting documentation not provided.<br>• Major effect on personnel health |

| Likelihood | Consequences/ Impact | | |
|---|---|---|---|
| | 1 – Minor | 2 – Moderate | 3 – Major |
| **1 (Unlikely)** | Low | Medium | High |
| **2 (Possible)** | Low | Medium | High |
| **3 (Likely)** | Medium | High | High |

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| . No | Process steps/component | Risk | GMP Risk Yes/No | Justification | Other Risk type | Justification | Risk Level | Risk Control | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method | Residual risk level | Verification |
| **Charging:** | | | | | | | | | | |
| 1. | Charging of material | Spillage during charging of material | Yes | Loss of quantity of the materials, result in disturbed proportion of the same, area contamination | EHS/ Operational | Product exposure. Product loss | High | Charging chute will be designed wide enough for appropriate feeding method of input materials | Acceptable | IQ / PQ |
| 2. | Charging vent | Material spreads out from the charging vent | Yes | Loss of quantity of the materials, result in disturbed proportion of the same, area contamination | EHS/ Operational | Product exposure. Product loss | High | Lid/Cover will be provided to stop powder to spreading out | Acceptable | IQ / PQ |
| **Process** | | | | | | | | | | |
| 3. | Sifting | Dead spots formed | Yes | Material will remain non-sifted | No | NA | Medium | Equipment should be designed so that there would not be any dead spot | Acceptable | OQ |
| 4. | Frame and sieve assembly | Frame and sieve assembly get loosen during operation | Yes | Malfunctioning of the sifting process | EHS | Accident due to detachment of parts. Product exposure. | High | Secure locking of the frame, gasket and sieve assembly will be considered so that it will remain tighten during entire sifting operation. | Acceptable | IQ / OQ |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method | Residual risk level | Verification |
| **Discharge:** | | | | | | | | | | |
| 5. | Discharge chute | Powder spreads out during transferring | Yes | Product loss | EHS | Product exposure | High | Discharge chute shall be designed to avoid the spillage using silica latex sleeve | Acceptable | IQ / PQ |
| 6. | Product discharge | Incomplete discharge of the product | Yes | Uniformity of content of product may get disturbed | No | NA | Medium | Vibrosifter will be designed to facilitate complete discharge of the product. Tangential slope will be provisioned at the discharge. | Acceptable | IQ / PQ |
| **Cleaning and Material of Construction:** | | | | | | | | | | |
| 7. | MOC | Product contact surface material is not cleanable | Yes | Uncleanable surface leads to product contamination | No | NA | High | Contact surfaces will be of SS 316 with internal mirror finish without crevices. Weld joints should be ground finish | Acceptable | IQ |
| 8. | MOC | Product non—contact parts are suitable for cleaning | Yes | Product contamination and susceptible for corrosion | No | NS | High | Product non contact metal surface would be of SS 304 or better | Acceptable | IQ |
| 9. | Machine parts | Parts cannot be dissembled | Yes | Proper cleaning will not be feasible | No | NA | High | Parts that cannot be cleaned in mounted position to be made suitable to dissemble and clean | Acceptable | IQ/ PQ |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method | Residual risk level | Verification |
| **Safety:** | | | | | | | | | | |
| 10. | Gaskets | Joint gaskets are not replaceable | Yes | Worn gasket will contaminate product and affect the integrity | EHS | Result in material leakage | Medium | All gaskets shall be replaceable | Acceptable | OQ |
| 11. | Gaskets | Gaskets are not compatible with material handled in equipment | Yes | Product contamination | No | NA | Medium | Gaskets will be made of approved food grade elastomer | Acceptable | IQ |
| 12. | Noise level | More noise is produced by the equipment during the operation | No | NA | EHS | High noise may cause deafness and anxiety | Medium | Noise level shall be below 80 db at a distance of 1 m from the equipment. | Acceptable | OQ |
| 13. | Closure of the rotating part | Appropriate closure of the rotating part is not provided. | No | No impact on the product | EHS | It may lead to accident | High | Appropriate closure of all the rotating parts. | Acceptable | IQ |
| 14. | Machine operation | Operator cannot set the machine | Yes | Process parameters cannot be achieved | Productivity | Machine cannot be operated | High | Proper training to be provided to concern person for setting and operation of machine | Low | OQ |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method | Residual risk level | Verification |
| 15. | Earthing | Improper earthing may lead to electric shock | No | No impact on product quality | EHS | Accident may take place die to generation of static charge | High | Proper earthing will be considered in the design | Acceptable | IQ |
| **Controlling** | | | | | | | | | | |
| 16. | Control system | Controlling of machine not possible | No | Process parameter could not be set/ adjusted | No | NA | High | Control panel/ relay shall be provided to control all process related parameter and to ensure effectiveness of process | Acceptable | IQ / OQ |
| **Documentation:** | | | | | | | | | | |
| 17. | Documentation | Critical surfaces are not tested for material of construction and test reports are not provided | Yes | Lack of documented evidence leads to question on the quality of MOC | No | NA | High | MOC description and certification of critical parts to be provided | Acceptable | IQ |
| 18. | Documentation | Instruments are not provided with calibration certificate | Yes | Calibration cannot be assured due to lack of documented evidence | No | NA | High | Critical instrumentation shall be supported with calibration certificates. | Acceptable | IQ / OQ |

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| | | | | | | | | Mitigation Method | Residual risk level | Verification |
| 19. | Documentation | Equipment is not provided with design and functional specification | Yes | Design qualification is not possible | No | NA | High | Design and functional specification should be supplied as per URS | Acceptable | IQ / OQ |
| 20. | Documentation | Equipment is not provided with Operation & maintenance manual | Yes | Correct operation is not ensured and Qualification requirement | No | NA | High | O & M manual should be supplied per URS | Acceptable | IQ / OQ |
| 21. | Standard Operating procedure | Standard operating procedures are not available. | Yes | Procedures critical operations cannot be carried out successfully resulting process failure. | Operational | Productivity will get decrease to unavailability of procedure. | High | SOPs for Operation, Cleaning and maintenance shall be prepared in line with operational and maintenance manual and finalized. | Acceptable | IQ / OQ |

# FAILURE MODE EFFECT ANALYSIS FOR VIBRO SIFTER

| Acronym | Definition |
|---|---|
| cGMP | Current Good Manufacturing Practice |
| db | Decibel |
| EU-GMP | European –Good Manufacturing Practice |
| GA | General Arrangement |
| GAMP | Good Automated Manufacturing Practices |
| GMP | Good Manufacturing Practices |
| HMI | Human Machine Interface |
| IQ | Installation Qualification |
| MOC | Material Of Construction |
| OQ | Operational Qualification |
| O & M | Operation and Maintenance Manual |
| PQ | Performance Qualification |
| SOP | Standard Operating Procedures |
| SS | Stainless steel |
| URS | User Requirement Specification |