|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.0 Environmental Health & Safety** | Yes | No | N/A | Comments |
| * 1. Complete EHS Questionnaire |  |  |  |  |
| * 1. MSDS for Drug Substance |  |  |  |  |
| * 1. MSDS for Excipients |  |  |  |  |
| * 1. Toxicity Data |  |  |  |  |
| * 1. API exclusivity data (If Available) |  |  |  |  |
| **2.0 Materials** |  |  |  |  |
| **2.1 Drug Substance** |  |  |  |  |
| 2.1.1 Vendor Specification / CofA |  |  |  |  |
| 2.1.2 Sample of CofA, (Supplier/Sending unit) Including Bulk / Tap density and PSD data. |  |  |  |  |
| 2.1.3 BSE/TSE Statement |  |  |  |  |
| 2.1.4 Residual Solvent Statement |  |  |  |  |
| Metal Catalyst Residues statement  Genotoxic impurities statement (if applicable)  Melamine statement |  |  |  |  |
| 2.1.5 Letter Stating GMP status of manufacturer (if non-compendial) |  |  |  |  |
| 2.1.6 Import Routing Guide |  |  |  |  |
| 2.1.7 Memo to outline Micro Validation requirements or waiver |  |  |  |  |
| 2.1.8 Allergen letter (if applicable) |  |  |  |  |
| 2.1.9 API registration referential : CEP, DMF, scientific data) |  |  |  |  |
| 2.1.10 API Letter Stating Stability Data, including the requirement of temptales during shipment. |  |  |  |  |
| 2.1.11 API supplier Audit report |  |  |  |  |
| 2.1.12 API supplier inspection |  |  |  |  |
| 2.1.13 API shipping container |  |  |  |  |
| 2.1.14 API packaging container (pictures) |  |  |  |  |
| 2.1.15 API critical handling information (e.i. light, moisture, oxygen, and/or heat sensitive, use of solvents) |  |  |  |  |
| 2.1.16 API shelf life |  |  |  |  |
| 2.1.17 API holding time, retest period |  |  |  |  |
| **2.2 Excipients** |  |  |  |  |
| 2.2.1 Vendor Specification / CofA |  |  |  |  |
| 2.2.2 Sample of CofA (including bulk, tap density and PSD data) |  |  |  |  |
| 2.2.3 BSE/TSE Statement |  |  |  |  |
| 2.2.4 Residual Solvent Statement |  |  |  |  |
| 2.2.5 Letter Stating GMP status of manufacturer (if non-compendial) |  |  |  |  |
| 2.1.6 Validated Test Methods (If non-compendial) and method validation reports |  |  |  |  |
| 2.1.7 Memo to outline Micro Validation requirements or waiver |  |  |  |  |
| 2.1.8 Allergen letter (if applicable) |  |  |  |  |
| **2.3 Packaging Components** |  |  |  |  |
| 2.3.1 Vendor Specification |  |  |  |  |
| 2.3.2 Sample CofAs |  |  |  |  |
| 2.3.3 Art Work |  |  |  |  |
| BSE/TSE statement (if applicable) |  |  |  |  |
| **3.0 Analytical / Micro Methods** |  |  |  |  |
| 3.0.1 Inter-laboratory Qualification Protocol and Report |  |  |  |  |
| **3.1 Drug Product Cleaning Residual Method** |  |  |  |  |
| 3.1.1 Cleaning Method and Validation Report |  |  |  |  |
| 3.1.2 Cleaning Validation Residual Limit Form |  |  |  |  |
| 3.1.3 API solubility, viscosity and density data |  |  |  |  |
| 3.1.4 API stability data |  |  |  |  |
| 3.1.5 API Structure |  |  |  |  |
| 3.1.6 API Molecular weight |  |  |  |  |
| 3.1.7 LTD (Lowest Therapeutic Dose) / MDI (Maximum Daily Intake) |  |  |  |  |
| **3.2 API Methods** |  |  |  |  |
| 3.2.1 API Methods |  |  |  |  |
| 3.2.2 API Method Validation and Report |  |  |  |  |
| **3.3 Drug Product** |  |  |  |  |
| 3.3.1 Product Methods |  |  |  |  |
| 3.3.2 Product Methods Validation and Reports |  |  |  |  |
| 3.3.3 Micro Methods |  |  |  |  |
| 3.3.4 Micro Methods Validation and Reports |  |  |  |  |
| 3.3.5 Memo outlining Micro Validation Requirements. |  |  |  |  |
| 3.3.6 In-process Specifications |  |  |  |  |
| 3.3.7 Release Specifications for Bulk |  |  |  |  |
| 3.3.8 Release Specifications for Finished Product |  |  |  |  |
| 3.3.9 Release Specification for WIP – Blend, Cores (if applicable) |  |  |  |  |
| 3.3.10 Bulk density, tapped density, particle size analysis |  |  |  |  |
| 3.3.11 Analysis results for the last 20 batches |  |  |  |  |
| **4.0 Stability** |  |  |  |  |
| 4.1 Stability Specifications |  |  |  |  |
| 4.1 Specific Stability Methods and Methods Validation Reports |  |  |  |  |
| 4.2 Expiry Date |  |  |  |  |
| **5.0 Manufacturing** |  |  |  |  |
| 5.1 Formulation |  |  |  |  |
| 5.2 Process Flow Chart |  |  |  |  |
| 5.3 Tooling drawing or requirements |  |  |  |  |
| 5.4 Executed Batch Records or Blank Batch Records |  |  |  |  |
| 5.5 Bill of Materials |  |  |  |  |
| 5.6 Process Development Reports (If available) |  |  |  |  |
| 5.7 In Process Testing and Acceptance Criteria |  |  |  |  |
| 5.8. Hold Time Studies for each manufacturing stage |  |  |  |  |
| 5.9. Process Critical Steps Summary |  |  |  |  |
| 5.10 Lyo characterization (if applicable) |  |  |  |  |
| 5.11 Lyo cycle recipe and executed chart (if applicable) |  |  |  |  |
| 5.12 Equipment (including description and suppliers) |  |  |  |  |
| 5.13 Product Samples (If available) |  |  |  |  |
| **6.0 Packaging** |  |  |  |  |
| 6.1 Process Flow Chart |  |  |  |  |
| 6.2 Tooling drawing or requirements |  |  |  |  |
| 6.3 Executed Batch Records or Blank Batch Records |  |  |  |  |
| 6.4 Packaging Bill of Materials |  |  |  |  |
| 6.5 Packaging Equipment Qualification |  |  |  |  |
| 6.6 Packaging Development Reports (If available) |  |  |  |  |
| 6.7 In Process Testing and Acceptance Criteria |  |  |  |  |
| 6.8 Equipment (including description and suppliers) |  |  |  |  |
| 6.9 Packaging Samples (If available) |  |  |  |  |
| **7.0 Markets / Regulatory** |  |  |  |  |
| 7.1 Markets |  |  |  |  |
| 7.2 Regulatory Requirements |  |  |  |  |
| 7.3 Copy of Product License (Implementation, renewal, amendments) |  |  |  |  |
| 7.2 Copy of Pharmaceutical Documentation( part II in effect on each country or any official reference document) |  |  |  |  |
| **8.0 Product History** |  |  |  |  |
| 8.1 Complaints |  |  |  |  |
| 8.2 Deviations |  |  |  |  |
| 8.3 OOS |  |  |  |  |
| **9.0 Other** |  |  |  |  |
| 9.1 Annual Product Review (If available) |  |  |  |  |
| 9.2 Shipping Study |  |  |  |  |