| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Formulation, Research and Development | **SOP No.:** |
| **Title:** Handling of Site Transfer Projects | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

**1.0 OBJECTIVE:**

To lay down a procedure for Handling of Site Transfer Projects.

**2.0 SCOPE:**

This SOP is applicable to Formulations, Research and Development and Production.

**3.0 RESPONSIBILITY:**

3.1 Group Leader – FR&D, AD, Production, RA, QA will be responsible for planning and coordination of activities.

3.2 Head – FR&D and Manager-QA are responsible for implementation and compliance

**4.0 DEFINITION(s):**

Not Applicable

**5.0 PROCEDURE:**

5.1 The following details shall be collected from the location (wherever applicable) from which the product is planned for the transfer.

5.1.1 Product Manual
5.1.2 Development Report
5.1.3 Master batch manufacturing record and Batch packing record
5.1.4 List of Equipment used in the manufacture
5.1.5 In-process Control checks
5.1.6 Validation of manufacturing process
5.1.7 Specification and Standard test procedure – Active
5.1.8 Specification and Standard test procedure – Excipients
5.1.9 Specification and Standard test procedure – packing materials
5.1.10 Specification and Standard test procedure – In-process and Finished product
5.1.11 Analytical method validation report for the Raw material, In-process and Finished product.
5.1.12 Stability Specification and Standard test procedure
5.1.13 Stability data
5.1.14 Conclusion of Stability studies, Shelf life and storage condition
5.1.15 Method validation of the stability indicating method
5.1.16 Bio-availability / Bio-equivalence Report
5.1.17 Toxicological and Pharmacological Information
5.1.18 Clinical Information
5.1.19 Dossier Information
5.1.20 Package Insert
5.1.21 Vendor qualification reports of raw materials
5.1.22 Lay outs of tooling and change parts
5.1.23 Product samples for comparison studies along with certificate of analysis.

5.2 Specifications, standard test procedures, batch documents shall be

translated to standard formats and any additional data which can not be fitted into standard formats shall be enclosed as annexure.

5.3 If vendor qualification checklist satisfy the existing system, vendor list shall be updated using the above vendor qualification report as supportive document.

5.4 Three production batches preferably with commercial batch sizes or batch size more than 1/10$^{th}$ size of commercial batch size shall be planned.

5.5 Process validation shall be completed on these batches.

5.6 Physico chemical equivalence of the product shall be established with the samples obtained from parent location.

5.7 Multi point dissolution equivalence shall be established.

5.8 Stability protocol shall be prepared and the batches shall be charged for stability as per the protocol.

5.9 Technology transfer document shall be signed off between parent location and site.

5.10 Analytical method transfer document shall be signed off between two locations.

**6.0 REFERENCE(s):**

Not Applicable

**7.0 ABBREVIATION(s):**

| Abbreviation | Full Description |
|---|---|
| SOP | Standard Operating Procedure |
| QA | Quality Assurance |
| FR&D | Formulations, Research and Development |
| AD | Analytical Development |
| RA | Regulatory Affairs |

**8.0 FLOWCHART(s):**

Not Applicable

**9.0 ANNEXURE(s):**

Not Applicable