| STANDARD OPERATING PROCEDURE | |
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## 1.0 OBJECTIVE:

To lay down a Procedure for Technology Transfer.

## 2.0 SCOPE:

This SOP is applicable to Technology Transfer at ……...

## 3.0 RESPONSIBILITY:

**QA (Officer/ Executive):** Preparation, Distribution (to Respective Departments), Revision, Retrieval & Destruction of this SOP.

**Manager QA:** Review, Approval, Training and Effective implementation of this SOP in all the applicable areas. To verify the accuracy, adequacy, completeness and correctness of documents as per the checklist.

**Head Production:** Review of contents of Protocols and Reports. Review of Protocol & Report, and timely implementation of the Procedure.

**Head Engineering:** To review in accordance to engineering aspect.

**Manager QC:** To review technology transfer Protocol report in accordance to Analytical aspect.

**Packing and Development:** To ensure the development, designing and verification of artwork.

**Representative Customer/Party/Site:** To monitor the batch processing jointly with receiving unit personnel during execution.

## 4.0 ACCOUNTABILITY:

**Head QA:** Authorization of this SOP & ensure Training and effective Implementation of SOP. Approval of Technology transfer document.

**Head Production:** To approve the Protocol Report for Technology Transfer.

**Head QA (SU):** Timely sending of technology transfer document after reviewing for their adequacy, accuracy, completeness and correctness.

**Head QA (RU):** Followup and timely review of technology transfer activity for their adequacy, accuracy, completeness and correctness.

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**5.0 DEFINITION:**

**5.1 Critical Process Parameter (CPP):** A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

**5.2 Critical Quality Attributes:** A CQA is a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality. CQAs are generally associated with the drug substance, excipients, intermediates (in-process materials), and drug product.

**5.3 Gap analysis:** Identification of critical elements of a process, which are available at the SU but are missing from the RU.

**5.4 Inter-company transfer:** A transfer of technology between sites of different companies.

**5.5 Intra-company transfer:** A transfer of technology between sites of the same group of companies.

**5.6 Receiving unit (RU):** The involved disciplines at an organization where a designated product, process or method is expected to be transferred.

**5.7 Sending unit (SU):** The involved disciplines at an organization where a designated product, process or method is expected to be transferred from.

**5.8 Technology Transfer:** The systematic procedure that is followed in order to pass the documented Knowledge and Experience gained during Product Development and / or Commercialization to an appropriate, responsible and Authorized Party.

**5.9** Technology Transfer involves not only the Transfer of Documents but also includes the demonstrated ability of a receiving unit to effectively carryout the Critical Elements of Transferred Technology to the satisfaction of all Parties and any or all-applicable Regulatory Bodies.

**5.10** Transfer of technology is defined as “a logical procedure that controls the transfer of an established process together with its documentation and professional expertise to a site capable of reproducing the process and its support functions to a predetermined level of performance”.

**5.11 Validation protocol (or plan) (VP):** A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing process – or a part thereof – for routine use.

**5.12** **Validation report (VR):** A document in which the records, results and evaluation of a completed validation programme are assembled and summarized. It may also contain proposals for the improvement of processes and/or equipment.

**6.0** **PROCEDURE:**

**6.1** Technology Transfer can be done between Unit to Unit/Customer (Third party) to Unit for Process/Product associated with API/ANDA along with documents including Change Control, Process Flow of Processing/Packing, Equipment qualification, Cleaning validation, Process Validation, Training, SOP's, Analytical Method etc.

**6.2** A comprehensive technical gap analysis shall be performed between the SU and RU including technical risk assessment and potential regulatory gaps, as needed.

**6.3** In case of new product transferred from Unit/Customer to pilot plant or from Unit/Customer to take scale up or exhibit batches the Process validation and Analytical method suitability document shall be transferred.

**6.4** Process validation shall be done as per **SOP**

**6.5** If appropriate, the Receiving Unit QC should run the methods and identify any issues that may need to be re-solved, before finalizing the transfer protocol through **"Gap Analysis Equivalency Report" Annexure-V**.

**6.6** Analytical Method Transfer shall be done as per Respective SOP

**6.7** QA shall ensure Agreement between Unit/Customer and receiving Location QA as per format shown in **Annexure-VI**, Titled **"Checklist for Technology Transfer Documents"** in case of transfer of either new process or existing process.

**6.8** After signing of the agreement, the numbering of Technology Transfer protocol report shall be logged by QA.

**Numbering System for Technology Transfer Protocol Report:**

Number shall be assigned as **TT/YY/NNNN**,

**Where,**

| | | |
|---|---|---|
| TT | : | Denotes Technology Transfer |
| / | : | separator |
| YY | : | Last two digit of Year |

/ : separator

NNNN : Stands for Serial Number, starting from **0001**.

**Example:** TT/21/0001; Denotes first Technology Transfer Protocol report raised for in year 2021.

**6.9** Technology transfer protocol report shall be prepared, reviewed and approved by the receiving unit QA along with the subject matter expert of various departments.

**6.10** The Head user department/designee shall prepare the equivalency checks (But not limited to) for process/product/method as mentioned in the protocol report along with the Gap analysis within the equipment as per **Annexure-V**.

**6.11** In case of exhibit batch, batch size is increased then an equivalence report shall be in-place to meet the predefined judgment criteria with respect to design, reproducibility of results and quality. The following documents and equivalency shall be ensured as per the **Annexure-V** and **Annexure-VI**.

**6.12** Each checklist shall be reviewed by Head of user department and approved by Head QA.

**6.13** Successful execution of each step shall be documented in validation report through template. The template shall be applicable for each Equipment/Instrument/Spares/Product/Process/Method and their parameters.

**6.14** In case of any problem arises QA along with production and QC shall investigate and refer to site/customer through Investigation report. Any deviation/changes in the process shall be supported by the Quality Management system.

**6.15** Upon compilation of report, the same shall be forwarded to subject matter expert of various departments of sender as well as receiver for review and approval as per **Annexure-II**.

**6.16** The RU shall ensure that trained personnel are in place before validation of the process to be transferred. The Sending Unit should provide training to the Receiving Unit when required. This shall include a review of the methods and transfer protocol, as well as laboratory work, if possible. Training should be documented.

**6.17 FOLLOWING REQUIREMENTS SHALL BE COVERED/STUDIED DURING TECHNOLOGY TRANSFER:**

**6.17.1** All Technology Transfer Documents shall be handed over to QA Department for Verification and Approval from Head Manufacturing and Authorized by Head QA.

**6.17.2** Site / Customer shall transfer Master Formula Record (MFR), BMR & BPR, Batch Manufacturing Record & Batch Packing record and Standard Test Specification (STS)

and Standard Test Procedures (STP) of API, Excipients, Inprocess, Semi-finished and Finished Product.

**6.18 FOLLOWING INFORMATION SHALL BE PROVIDED RELATED TO API and EXCIPIENTS:**

Information needed in each specific case shall be assessed using principles of Quality Risk Management wherever required.

**6.18.1** The function of each API and Excipients included in the Formulation shall be identified.

**6.18.2** Name and address for Manufactures of each API and Excipients.

**6.18.3** Specification for all API, Excipients, which includes compendial, and Non-compendial Excipients.

**6.18.4** Recommendation and justification for special handling precautions shall be provided.

**6.18.5** Residual Solvents and OVI's information for API and Excipients (as applicable).

**6.18.6** If necessary, appropriate Solubility Data shall be included.

**6.18.7** Health and Safety Assessment of all Materials and Process shall be included.

**6.18.8** Environmental Assessment of all Materials and Process shall be included.

**6.18.9** Flow chart of synthesis pathway, outline of process, Critical Process Parameters, Process control parameters etc. shall be taken into consideration.

**6.19 THE FOLLOWING PROCESS INFORMATION SHALL BE INCLUDED BUT NOT LIMITED TO:**

**6.19.1** Premises and Equipment Selection / Material of Construction shall be included.

**6.19.2** Equipment Qualification status shall be included.

**6.19.3** In process control of Products shall be included.

**6.19.4** Identification of Process Control points shall be identified.

**6.19.5** Identification of Process Critical Quality Attributes shall be identified.

**6.19.6** Qualification of In-Process Hold Times / Conditions (Between Two Manufacturing Steps) shall be identified.

**6.19.7** Raw Material Order / Method of Addition shall be mentioned.

**6.19.8** Bulk Transfers (between Processing Steps) shall be mentioned.

**6.20 CRITICAL ASPECT OF DOSAGE FORM SHALL BE INCLUDED BUT NOT LIMITED TO THE FOLLOWING:**

**6.20.1** Critical Process Parameters (CPP) shall be Optimized and Documented.

**6.20.2** Information about Sampling Techniques with Diagram of Sampling Location shall be mentioned.

**6.20.3** The Utility layout supporting the Critical Equipment Requirements to Manufacture the Product shall be included.

**6.20.4** The Transition or Movement of Raw Materials, Drug substances Drug Product, Components and Personnel shall be considered.

**6.20.5** Storage Requirements of Raw Materials, Packing material, Inprocess, (SFG) and Finished Products and information on arrangement of retention samples.

**6.20.6** Process Validation Report.

**6.20.7** Analytical Methodology.

**6.20.8** Stability Information.

**6.20.9** Cleaning Procedures and its Validation with Recovery Studies shall be documented.

**6.21 FOLLOWING INFORMATION RELATED TO PACKING COMPONENT SPECIFICATION SHALL BE INCLUDED:**

**6.21.1** Detailed Specification for each Packing Components shall be specified.

**6.21.2** Labeling Requirements and its Study Aspects shall be mentioned.

**6.21.3** In-process Controls and Test Methods shall be documented.

**6.22 FOLLOWING DOCUMENTS SHALL BE TRANSFERRED FROM SITE AND OTHER LOCATIONS:**

**6.22.1** Raw Material Specifications

**6.22.2** Intermediate Product Specifications

**6.22.3** Packaging and Finished Product Specifications

**6.22.4** Master Formula Record

**6.22.5** Approved Vendor list

**6.22.6** Special Storage, Handling and Cleaning Information’s

**6.22.7** Method of Inprocess and Intermediate Bulk Analysis

**6.22.8** Analytical Method Specifications and Method of analysis

**6.22.9** Process Validation Protocol and Report of Transferred Products

**6.22.10** Standard Operating Procedures and Standard Test Procedures

**6.22.11** Sampling Plans and Sampling Methods

**6.22.12** Batch Coding and Numbering System

**6.22.13** Labeling and Packaging Specifications

**6.22.14** Environmental Specifications and condition

**6.22.15** Trend Analysis and History Data of Products

**6.22.16** Product Development report

**6.22.17** Quality Risk Assessment

**6.22.18** Annual Product Quality Review

**6.23** For Successful Transfer of Technology, as per **Annexure-II** shall be jointly prepared by the SU and the RU should execute the transfer protocol and jointly prepare transfer report along with Location QA, Production and desired SME of respective area as per the Protocol report.

**6.24** Initial Three Optimization Batches shall be taken in presence of Concerned Location Personnel (SU), from where Technology being transferred.

**6.25** The Optimization Batches shall be validated by Production and Approved by Head QA.

**6.26** All critical process parameters and finished product batches shall be assessed at receiving unit.

**6.27** After Validation, QA shall prepare Master Formula Record (MFR), which shall be approved by Head QA and Authorized by Head Quality .

**6.28** All Analytical Methods for RM, PM, In-process, SFG, finished product shall be first checked in presence of Concerned Location Personnel (SU), (If required).

**6.29** QA shall review the Process Validation Protocol and Report as per the observation and results. In case of deviations from Acceptance Criteria, QA shall inform Concerned Location Personnel (SU), for necessary modification in Formulation and Documentation.

**6.30** Any change in Manufacturing Process, Batch Size, Quality of Material, Capacity of Equipments and Acceptance Criteria shall be made only after getting Approval from Site unit.

**6.31** If necessary, QA shall make relevant changes in MFR and BMR & BPR in consultation with Production and Site unit.

**6.32** For the Technology Transfer, Product Development Data, Optimization Batches and Validation Batches shall be considered.

**6.33** Production Manager shall review and QA Manager shall verify Technology Transfer Report.

**6.34** Head Operation shall recommend and Head QA shall authorize the Technology Transfer Report.

## 7.0 ABBREVIATION:

| | |
|---|---|
| ANDA | Abbreviated New Drug Application |
| API | Active Pharmaceutical Ingredients |
| BSE | Bovine Spongiform Encephalopathy |
| CPP | Critical Process Parameters |
| CQA | Corporate Quality Assurance |
| Ltd. | Limited |
| MFR | Master Formula Record |
| OVI | Organic Volatile Impurities |
| PM | Packaging Material |
| Pvt. | Private |
| QA | Quality Assurance |
| RM | Raw Material |
| RU | Receiving Unit |
| SFG | Semi Finished Goods |
| SOP | Standard Operating Procedure |
| STP | Standard Test Procedures |
| SU | Sender Unit |
| TRS | Technical Report Series |
| TSE | Transmissible Spongiform Encephalopathy |
| URS | User Requirement Specification |
| WHO | World Health Organization |

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## 8.0 ANNEXURES:

| ANNEXURE No. | TITLE OF ANNEXURE | FORMAT No. |
|---|---|---|
| Annexure-I | Agreement of Technology Transfer | |
| Annexure-II | Technology Transfer Protocol Report for Product Transfer (Specimen) | |
| Annexure-III | Technology Transfer Log | |
| Annexure-IV | Flow Chart for Technology Transfer | |
| Annexure-V | Gap Analysis Equivalency Report for Technology Transfer | |
| Annexure-VI | Checklist for Technology Transfer Documents | |

## 9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.

## 10.0 REFERENCES:

- WHO TRS 961 Annex 7 WHO Expert Committee on Transfer of Technology in Pharmaceutical Manufacturing
- ICH Q10 Pharmaceutical Quality System
- ICH Q8 R2 Pharmaceutical Development
- ISPE Guide Technology Transfer 2003

## 11.0 REVISION HISTORY:

| Revision No. | Change Control No. | Details of Changes | Reason of Changes | Effective Date | Done By |
|---|---|---|---|---|---|
| 00 | Not Applicable | Not Applicable | New SOP | | |

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## ANNEXURE–I
## AGREEMENT OF TECHNOLOGY TRANSFER

**Date:**

Here with Site/Customer of……..……..……is agree to Transfer Technology of Product Name…… (Dosage form……..…) from……...to……..……....

- Site shall provide Master Formulation Record, Finished Product Specifications, Standard Test Procedures of Active Pharmaceutical Ingredients, Semi-finished, Finished drug, Finished substances and other Excipients in case of new products.
- Site shall provide Batch Production Control Record, Batch Packaging Record in case of existing products.
- Site unit shall take trial of first three Batches of product transferred in presence of Production and QA of……..……
- Site shall also provide assistance in troubleshooting whenever required.
- Production shall prepare Batch Manufacturing Record and Batch Packaging Record, RM, PM, Inprocess and Finished Product Specifications and Validation Protocol and Report at Location.
- Any change in Manufacturing Process Batch Size, Quality of Material, Capacity of Equipments and Acceptance Criteria shall be informed to QA & customer.
- If necessary, Production shall make relevant changes in Master Formula Record, BMR & BPR in consultation with QA.
- Not limited to as the content may vary based on the agreed requirement between Site/Customer to Site.

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**ANNEXURE-II**

| | | | |
|---|---|---|---|
| | **TECHNOLOGY TRANSFER PROTOCOL REPORT** | **PROTOCOL REPORT No.:** | |
| | | **REVISION No.:**00 | |
| | | **EFFECTIVE DATE:** | |
| | | **PAGE No:**11 of 22 | |

**Page 01**

**Technology transfer Protocol report No.: _____**

**TECHNOLOGY TRANSFER**

**PROTOCOL REPORT**

**FOR**

**PRODUCT TRANSFER**

**FROM _____ TO _____**

**PRODUCT NAME _____**

| | |
|---|---|
| **LABEL CLAIM** | |
| **PRIMARY PACKING CONFIGURATION** | |
| **SHELF LIFE :** | |
| **STORAGE** | |

## PROTOCOL REPORT CONTENTS
## PROTOCOL CONTENTS

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## 1.0 PRE APPROVAL PROTOCOL REPORT:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (TECHNOLOGY TRANSFER) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| EXECUTIVE/MANAGER (QUALITY ASSURANCE) | | | |
| HEAD ( PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |
| HEAD (QUALITY CONTROL) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |

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**Other Pages**

## 2.0 OBJECTIVE:

To Design the technology transfer protocol report for successfully transfer the product (_____) manufacturing & analytical procedures from _____ to …….

## 3.0 SCOPE:

This Protocol Report is applicable for Technology Transfer System for requirements and actions necessary to effectively plan and execute a successful transfer of all formulations and products for various dosage forms that are proposed to be transferred from _____ to ……..

## 4.0 RESPONSIBILITY:

| DEPARTMENTS | RESPONSIBILITIES |
|---|---|
| **Technology transfer** | • Preparation, review & execution of Protocol Report.<br>• To arrange all the Existing Documents & Protocols like MFR/BMR/BPR/Specifications /Testing Procedures/Process validation/Method Validation/Cleaning Validation/ Stability Study/Hold Time Study Protocol.<br>• To Review the documents and gap analysis of Technology |
| **Production** | • To review the Protocol Report.<br>• To provide all the applicable documentation necessary for Technology Transfer. |
| **Quality Control** | • To Review the Protocol Report.<br>• To provide all the applicable documentation necessary for Technology Transfer. |
| **Engineering** | • To review protocol report in preview of engineering aspects.<br>• To provide all Engineering related support required for technology transfer. |
| **Quality Assurance** | • To Review the check list and gap analysis of Technology<br>• Review & authorized the Protocol Report.<br>• To prepare the all documents on plat format as per technology received. . |

## 5.0 TECHNOLOGY TRANSFER PROCESS:

- The product is developed / established at _____ and being transferred to new location i.e. _____ with an assurance that same equipments related to manufacturing & laboratory shall be used at _____.
- A copy of required documents are attached as per **Annexure-VI**.
- All the manufacturing and analytical activities at _____ will be performed as per the existing documents of _____.

- Existing documents checklist attached with the Technology Transfer Protocol Report mentioned as per **Annexure-II**.
- Annexure of **Gap Analysis Equivalency Report for Technology Transfer,** attached with the Technology Transfer Protocol Report mentioned as per **Annexure-V**.

## 6.0 PROCEDURES AND DOCUMENTATION OF TECHNOLOGY TRANSFER:

### 6.1. Organization For Technology Transfer

Technology Transfer from _____ to _____.

### 6.2. TECHNOLOGY TRANSFER PLAN:

Documents as per **Annexure-VI** (Checklist) will be provided from Provider Location to Receiving Location for New and Existing Product / Process.

Annexure of **Gap Analysis Equivalency Report for Technology Transfer**, attached with the Technology Transfer Protocol Report mentioned as per **Annexure-V**.

### 6.3. TECHNOLOGY TRANSFER REPORT:

The In-charge of the Receiving Location will ensure that each document has been delivered before the manufacturing of batches and verify the status of documents received as per the checklist.

### 6.4. REVIEW AND AUTHORIZED BY QUALITY ASSURANCE DEPARTMENT

The Technology Transfer documents will be approved by Head of Quality Assurance of Sender Location and accepted by Head of Quality Assurance of Receiving location.

### 6.5. IMPLEMENTATION OF TECHNOLOGY TRANSFER

The Technology Transfer documents along with all Annexure shall be delivered to Head Quality Assurance of Receiving Location to ensure that all documents like MFR, BMR & BPR, Specifications, SOP, STP, Process Validation, Hold Time and Stability, Cleaning, Analytical Protocols produced for his location for its correctness, accuracy, adequacy and completeness before commencement of production.

### 6.6. POINTS OF CONCERN FOR POST MARKETING TECHNOLOGY TRANSFER

The Technology Transfer for the production of commercial batches will be transferred before any batch is produced at Receiving Location and it shall be ensured that first three batches produced at Receiving Location are subjected to established studies.

## 7.0 OBSERVATION OF FIRST OPTIMIZED BATCH AT RECEIVING SITE:

### 7.1. During Batch Manufacturing:

| S.No. | Batch no. | Description of observation | Stage | Area | Comments |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**7.2. During analysis at Quality control:**

| S.No. | Batch no. | Description of observation | Stage | Area | Comments |
|---|---|---|---|---|---|
| | | | | | |

**8.0 ATTACHMENTS:**

1. Annexure of Check list & Gap evaluation report.

**9.0 DEVIATION:**_____

**10.0 CONCLUSION:**_____.

**11.0 RECOMMENDATION:**

_____

**12.0 ABBREVATIONS :**

| | | |
|---|---|---|
| TT | : | Technology transfer |
| BMR | : | Batch Manufacturing Record |
| BPR | : | Batch Packaging Record |
| QA | : | Quality Assurance |
| QC | : | Control |
| FP | : | Finished Product |
| MFR | : | Master Formula Record |
| PM | : | Packing Material |
| RM | : | Raw Material |
| RU | : | Receiving Unit |
| SOP | : | Standard Operating Procedure |
| STP | : | Standard Test Procedure |
| STS | : | Standard Test Specification |
| SU | : | Sender Unit |

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## 13.0 POST APPROVAL OF PROTOCOL REPORT

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (TECHNOLOGY TRANSFER) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| EXECUTIVE/MANAGER (QUALITY ASSURANCE) | | | |
| HEAD ( PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |
| HEAD (QUALITY CONTROL) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |

**STANDARD OPERATING PROCEDURE**

| | |
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## ANNEXURE-III
## TECHNOLOGY TRANSFER LOG

**Year:**

| S. No. | Technology Transfer No. | Logged by QA Sign & Date | Date of Agreement | Transfer from ____ to ____ | Sender Name & Address | Receiver Name & Address | Description of Product | Product Name | Dosage | Strength | Reference Change Control No. | QRA No. (if any) | Remark |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |

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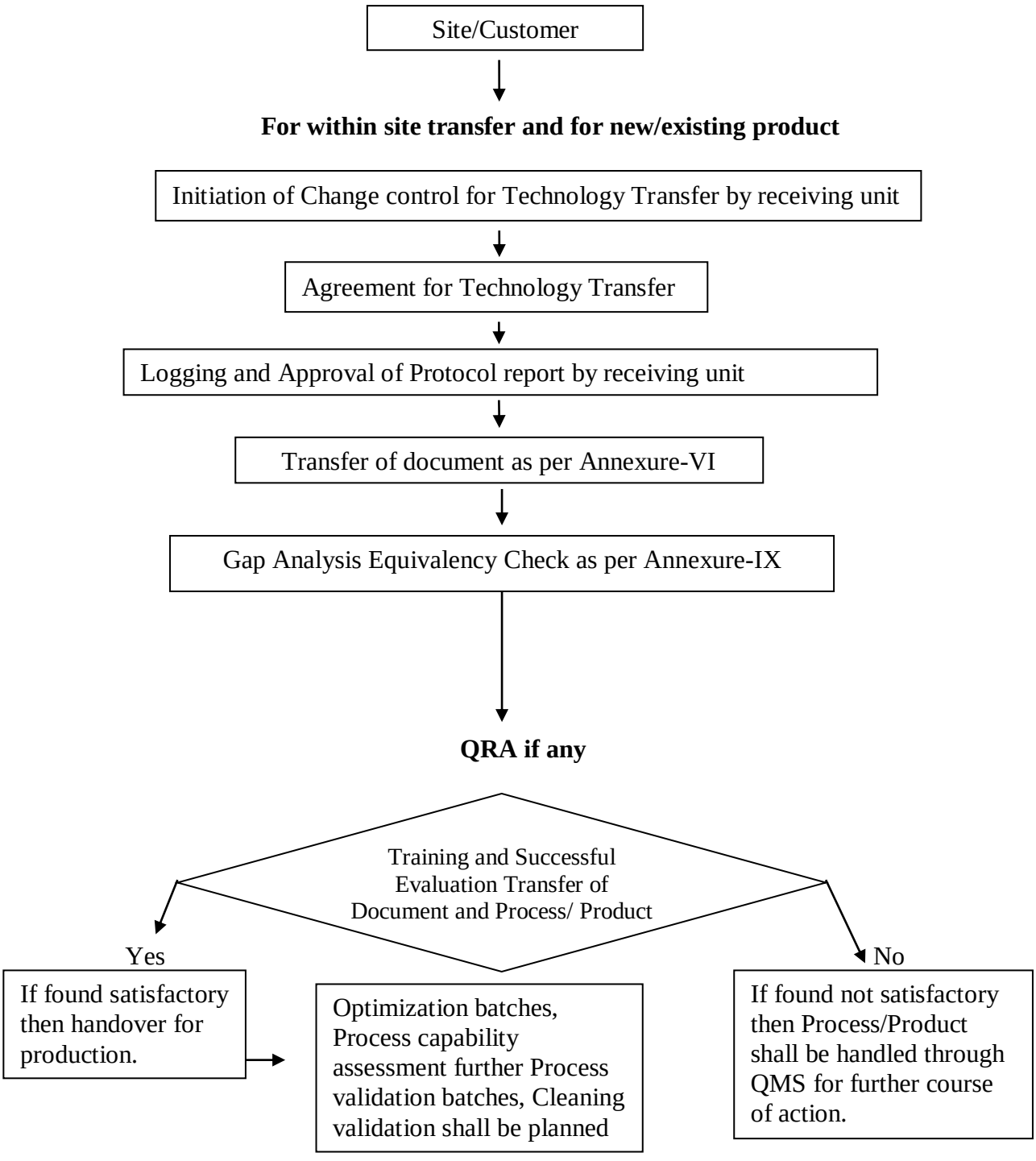
## ANNEXURE-IV

## FLOW CHART FOR TECHNOLOGY TRANSFER



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## ANNEXURE-V
## GAP ANALYSIS EQUIVALENCY REPORT FOR TECHNOLOGY TRANSFER

| GAP ANALYSIS EQUIVALENCY DATA VERIFICATION | | | | | | |
|---|---|---|---|---|---|---|
| **S.No.** | ***Type of Equipment/ Instrument/Spares** | ***Parameters** | **Sender Unit (SU) Equivalency** | **Receiving Unit (RU) Equivalency** | **Justification** | **Acceptance By QA Sign & Date** |
| 1. | | | | | | |
| 2. | | | | | | |
| 3. | | | | | | |
| 4. | | | | | | |
| 5. | | | | | | |
| 6. | | | | | | |
| 7. | | | | | | |
| 8. | | | | | | |
| 9. | | | | | | |
| 10. | | | | | | |

*But not limited to

QRA No. (if any) _____

**Conclusion:**

**Recommendation:**

**Sender Unit (SU) QA:** **Receiver Unit (RU) QA:** **Approved By Head QA (RU)**

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## ANNEXURE-VI
## CHECKLIST FOR TECHNOLOGY TRANSFER DOCUMENTS

**Technology Transfer Report No.:**

| S.No. | *List of Documents | Status (Received/Not Received) |
|---|---|---|
| 1. | Product Name | |
| 2. | Dosage of Product | |
| 3. | Strength | |
| 4. | DCGI Permission | |
| 5. | FDA Permission | |
| 6. | Product License No. | |
| 7. | Excise Formalities (If Applicable) | |
| 8. | Product Development Report | |
| 9. | Master Formula Record | |
| 10. | Batch Production & Control Record | |
| 11. | Process Validation Protocol/Report | |
| 12. | Analytical Method Validation Protocol/Report | |
| 13. | Cleaning Validation Protocol/Report | |
| 14. | Stability Study Protocol/Report | |
| 15. | Hold Time study Protocol and Report | |
| 16. | Annual Product Review | |
| 17. | SOP Index & All related SOPs | |
| 18. | Raw Material Specifications & Standard Testing Procedure | STS No.<br>STP No. |
| 19. | Packaging & Finished Product Specifications | STS No.<br>STP No. |
| 20. | Approved Vendor List | |
| 21. | Intermediate Product Specifications | STS No.<br>STP No. |
| 22. | Labeling & Packaging Specifications | STP No.<br>STP No. |
| 23. | Environmental Specifications | |
| 24. | Stability Study Data of scale up Batches (If not covered in PDR) | |
| 25. | Special Storage, Handling and Cleaning Information's (if any) | |
| 26. | Method of In-process and Intermediate Bulk Analysis | STS No.<br>STP No. |
| 27. | Analytical Method Specifications and Method of Analysis | STS No.<br>STP No. |
| 28. | Trend Analysis and History Data of Products | |
| 29. | Reprocessing/Rework | |
| 30. | MSDS of critical RM, PM, Intermediates and Drug products | |
| 31. | Impurity Profile | |

**STANDARD OPERATING PROCEDURE**

| | |
|---|---|
| **Department:** Quality Assurance | **SOP No.:** |
| **Title:** Technology Transfer | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

| S.No. | *List of Documents | Status (Received/Not Received) |
|---|---|---|
| 32. | Purity profile | |
| 33. | APQR | |
| 34. | Analyst Qualification | |
| 35. | Others | |

**Conclusion:**_____

**Recommendation:**_____

| Prepared By: | Checked By: | Verified By: |
|---|---|---|
| Officer /Executive | Head TT | Head QA |
| Sign & Date | Sign & Date | Sign & Date |