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1.0 PURPOSE

To define a procedure for transfer of analytical methods from one laboratory to other laboratory.

2.0 SCOPE

2.1 This procedure is applicable to the transfer of analytical method (drug substances and drug products) for assay, related substances, dissolution, preservative/antioxidant content, content uniformity, residual solvents and microbiological test or any other critical test for drug substances/drug products from one laboratory to other laboratories in …….

3.0 REFERENCE(S) & ATTACHMENTS

3.1 References

3.1.1 ICH- Validation of Analytical Procedures: Text and Methodology –Q2 (R1)

3.1.2 USP Chapter <1224> Transfer of analytical procedure

3.1.3 TRS -961 -2011 –Annex-7: WHO guideline on transfer of technology in pharmaceutical manufacturing.

3.2 Attachments

3.2.1 Attachment-I: Process flow chart for analytical method transfer.

3.2.2 Attachment-II: Pre-requisite checklist for analytical technology transfer from Transferring Laboratory to Receiving Laboratory

3.2.3 Attachment- III: Analytical Method Transfer Protocol

3.2.4 Attachment- IV: Analytical Method Transfer Report

3.2.3 Attachment- V: Analytical method transfer approval certificate.

3.2.4 Attachment-VI: Analytical method transfer training certificate.

4.0 DEFINITION & ABBREVIATION(S)

4.1 Definitions

4.1.1 **Transferring Laboratory:**

The laboratory that has conducted the original method development and method evaluation/ verification or the laboratory that has previously acted as receiving laboratory has successfully completed the analytical method transfer.

4.1.2 **Receiving Laboratory:**

The laboratory to which the analytical method is to be transferred.

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4.2 Abbreviations

4.2.1 API: Active Pharmaceuticals Ingredients

4.2.2 GC: Gas Chromatography

4.2.3 HPLC: High Performance Liquid Chromatography.

4.2.4 ppm: Parts Per Million.

4.2.5 QA: Quality Assurance.

4.2.6 QC: Quality Control.

4.2.7 RSD: Relative Standard Deviation.

4.2.8 RL: Receiving Laboratory

4.2.9 TL: Transferring Laboratory

5.0 RESPONSIBILITY

5.1 Corporate Quality Assurance

5.1.1 To prepare the guideline.

5.1.2 To ensure implementation of the guideline.

5.2 Transferring Laboratory:

5.2.1 To demonstrate analytical method to receiving laboratory.

5.2.2 To communicate with Receiving laboratory and resolve the issues of analytical method transfer.

5.2.3 To provide analytical method transfer package to receiving laboratory.

5.2.4 To provide pre-requisite to receiving laboratory.

5.2.5 To provide analytical method transfer protocol.

5.2.6 To provide proper training to receiving laboratory analysts stepwise during performing technology transfer activities (safety considerations, clear equations, any criticality of sample preparation and calculations etc.)

5.2.7 To provide only history/ issue trend, if any.

5.3 Receiving Laboratory:

5.3.1 To perform analysis as per standard test procedure provided by transferring laboratory.

5.3.2 To prepare standard test procedure, specification as per transfer package.

5.3.3 To report results and critical observation and preparation of analytical method transfer report.

5.3.4 To communicate results and observation of analytical method transfer with transferring laboratory.

5.4 Head QC or designee- Transferring & Receiving laboratory

5.4.1 To review and approve the analytical method transfer protocol.

5.4.2 To evaluate impact of the failure (if any) and decide further course of action.

5.4.3 To review the critical observation (if any) and take the necessary action.

5.4.4 To review and approve the report, training certificate and technology transfer certificate.

5.5 Quality Assurance Head:

5.5.1 To ensure implementation of system as per procedure.

5.5.2 To approve the protocol, report, training certificate and technology transfer certificate.

6.0 Distribution:

I. Quality Assurance

II. Quality Control

7.0 PROCEDURE:

7.1 General

7.1.1 After successful development and verification of analytical method, the transferring laboratory in consultation with receiving laboratory shall initiate the process by informing the receiving laboratory in advance of the proposed method transfer.

7.1.2 Transferring laboratory shall send a pre-requisite checklist of analytical method to receiving laboratory (any specific chemicals, reagents, reference standards, instruments, column required to receiving laboratory) as per Attachment-II.

7.1.3 Receiving laboratory shall review and verify the pre-requisite check list of analytical method to be transferred, procure all required reagents and ensure availability of required instruments and inform to transferring laboratory for method transfer.

7.1.4 In-house drug substance/drug product, analytical method shall be transferred. Compendial method shall not be transferred. Only method verification is required for compendial method. If there is any modification in compendial method then method transfer shall be required.

7.1.5 In the case of multiple strength of the same product for linear and non-linear, decision to be taken for analytical method transfer to be performed on which strength by transferring laboratory based on the criticality of the product and justification for rational shall be provided by the transferring laboratory.

7.2 Analytical method transfer

7.2.1 Transferring laboratory shall send the Analytical Method Transfer protocol as per Attachment-III to the receiving laboratory. Receiving laboratory shall review the protocol and shall be approved by Receiving and transferring laboratory.

7.2.2 Transferring laboratory shall analyze the sample of one batch of evaluation sample which is going to be sent to the receiving laboratory for tests and report the result. If a result of the sample meets the specification then transferring laboratory shall mention the same in the Certificate of Analysis (COA) and send it to receiving laboratory.

7.2.3 Transferring laboratory shall provide the analytical method transfer package to the receiving laboratory and receiving laboratory shall plan for tests for method transfer as mentioned in section 6.2.9.

7.2.4 Before execution of the activity for analytical method technology transfer, lab training and familiarization with the method to be transferred, shall be organized by transferring laboratory.

7.2.5 The analyst at both the laboratory (Transferring and receiving) shall perform analysis on the same batch.

7.2.6 The receiving laboratory shall use instrument that are equivalent to the transferring laboratory.

7.2.7 The sample shall be tested according to approved analytical method provided by Transferring laboratory.

7.2.8 Method transfer activity shall be recorded in respective analytical method transfer report format (Attachment- IV).

7.2.9 **Methodology and Acceptance Criteria:** Analytical method transfer activity shall be executed by 2 analysts (one analyst from the transferring laboratory and one analyst from the Receiving laboratory).

Test	Replicate of Tests	Acceptance Criteria
Identification	2 analyst (one analyst from each site)	The result of both analysis shall meet the requirement as per specification.
Assay	2 Analyst x 6 samples preparation (Prepare samples from same lot/ batch no. and analyse)	The results obtained by individual analyst % RSD for assay Analyst A: NMT 2.0 % Analyst B: NMT 2.0 % Overall RSD or both the Analyst NMT 3.0 %.
Content Uniformity/ Dose Uniformity*	2 Analyst x 10 dosage unit (Prepare samples from same lot/ batch no. and analyse)	Mean RSD of both analyst NMT 5.0 %. Overall RSD of both the analyst NMT 3.0 %.

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Test	Replicate of Tests	Acceptance Criteria
* Method transfer for content uniformity to be performed only if the assay method is different from content uniformity method.		
Preservative content/ Antioxidant	2 Analyst x 6 samples preparation (Prepare samples from same lot/ batch no. and analyse)	Individual analyst % RSD should be NMT 10.0 % The overall % RSD for results obtained by both the analysts should be NMT 15.0 %.
Dissolution/ % Drug Release	2 Analyst x 6 units (Prepare the dissolution samples on 6 units from same lot/ batch no. and analyse)	**Immediate Release-** RSD of six units of individual analyst NMT 5.0%. Overall RSD for both the analyst NMT 5.0%.
		Delayed Release- For Acid stage: It should meet the specification for both the analyst. For buffer stage: RSD of six units of individual analyst NMT 5.0%. Overall RSD for both the analyst NMT 5.0%.
		Modified Release- Mean result obtained of both analyst NMT 10.0% at each specified time point.
Related Substance/ compounds/ chromatography purity	2 Analyst x 6 samples preparation (Prepare samples from same lot/ batch no. and analyse)	**Case-1:** If the specification limit of impurities is less than and equal to 0.20%. The % RSD obtained by individual analyst and the overall % RSD for result obtained by both the analysts should be NMT 15.0. **Case-2:** If the specification limit of impurities is t more than 0.20%. The % RSD obtained by individual analyst should be NMT 10.0. The overall % RSD for result obtained by both the analysts should be NMT 15.0. **Case-3:** If the specification limit of impurities is less than and equal to 0.10%. The % RSD obtained by individual analyst should be NMT 25.0. The overall % RSD for result obtained by both the analysts should be NMT 25.0.
NOTE: Any unknown impurities below 0.05% and known impurities below LOQ shall not be compared.		

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Test	Replicate of Tests	Acceptance Criteria
Residual Solvents	2 Analyst x 6 samples preparation (Prepare samples from same lot/ batch no. and analyse)	If solvent content is more than 50 ppm and 50.0%, the difference of the means of each solvent result by 2 analysts should be NMT 20.0%. If solvent content is less than or equal to 50 ppm, the RSD of each results of residual solvents obtained by each analyst for each solvent shall NMT 15.0%.
Microbiological testing (Qualitative and Quantitative Limit tests)	Execute common on-site validation.	Demonstrate recovery of microorganism and recovery level with in acceptance limits specified in protocol or in Standard testing procedure.
Any other critical test	As per the protocol	As per the Specification

7.3 Method Transfer waiver: Subsequent to this transfer activity, if new strengths are added it shall be considered for a waiver/further transfer. The transfer waiver shall be taken in following cases:

7.3.1 If the newly added strength lies between lower and higher strengths of the transferred product, waiver shall be taken without any further justification.

7.3.2 However, if the proposed strength does not lie in between lower and higher strengths, it shall also be considered for waiver based upon the familiarity/ expertise of the method at the receiving laboratory. If any of the method are found critical based on the strength, same shall be considered for method transfer activity.

7.3.3 The new product composition is comparable to that of an existing product and/ or the concentration of the active ingredient is similar to that of an existing product and is analyzed by procedure with which the receiving laboratory already has experience.

7.3.4 The analytical procedure transferred is same as or very similar to a procedure already in use.

7.3.5 If eligible for method transfer product, the transferring laboratory shall provide document with appropriate justification.

7.4 Documentation:

7.4.1 Method transfer of all original documents pertaining to method transfer shall be achieved at Receiving Laboratory and Transferring Laboratory.

7.5 Assay

7.5.1 Six replicate assay shall be performed by both analysts from both the laboratories on the same sample at receiving laboratory.

7.5.2 **Acceptance criteria for drug substance/ drug product**

7.5.2.1 All the system suitability criteria shall comply as per the respective standard test procedure.

7.5.2.2 All the assay results shall comply as per the respective specification.

7.5.2.3 RSD of assay results obtained by each analyst shall be compared as mentioned in the above table.

7.5.2.4 Overall RSD obtained by each analyst shall also be compared as mentioned in the above table.

7.6 Content uniformity/Dose Uniformity

7.6.1 Test shall be performed on 10 dosage units sample preparation from same sample by both analysts at receiving laboratories (Total 20 analysis).

7.6.2 If the analytical method for the content uniformity test is equivalent to the assay method, i.e. standard and sample are prepared at equivalent concentrations, chromatographic system and system suitability criteria are the same, a method transfer for content uniformity need not be carried out.

7.6.3 **Acceptance criteria for content uniformity/dose Uniformity**

7.6.3.1 All the system suitability criteria shall comply as per the respective standard test procedure.

7.6.3.2 All the content uniformity results shall comply as per the respective specification.

7.6.3.3 RSD of content uniformity results of 10 dosage units obtained by each analyst shall not be more than 5.0 %.

7.6.3.4 Overall RSD for each analyst shall not be more than 3.0 %.

7.7 Related substances /Related Compound/ Chromatography Purity

7.7.1 Test shall be performed on six sample preparation from same sample by both analysts at receiving laboratories (Total 12 analysis).

7.7.2 **Acceptance criteria for related substances /related compound/ Chromatography Purity**

7.7.2.1 RSD of individual impurity and total impurities results of six preparations obtained by each analyst shall be compared as mentioned in the above table.

7.7.2.2 Overall RSD of individual impurity and total impurities results of 12 preparations obtained by both analysts shall also be compared as mentioned in the above table.

NOTE:

For any unknown impurities below 0.05% and known impurities below LOQ shall not be compared.

7.8 Residual solvent

7.8.1 Test shall be performed on six sample preparation for same sample by both analysts at the receiving laboratories (Total 12 analysis).

7.8.2 Acceptance criteria for residual solvent

7.8.2.1 All the system suitability criteria shall comply as per the respective standard test procedure.

7.8.2.2 All the results of residual solvent shall comply as per the respective specification.

7.8.2.3 RSD of the results of residual solvents obtained by each analyst for each solvent shall be compared as mentioned in the above table.

7.8.2.4 The difference of the means of each solvent determined by the two analyst of each laboratory (inter–laboratory) shall be compared as mentioned in the above table.

7.9 Preservative / Antioxidant content

7.9.1 Analyst of both laboratory shall test six sample preparations each.

7.9.2 **Acceptance criteria for Preservative / Antioxidant content**

7.9.2.1 All the system suitability criteria shall comply as per the respective standard test procedure.

7.9.2.2 All the results of preservative content shall comply as per the respective specification.

7.9.2.3 RSD of the six results of each analyst shall not be more than 10.0 %.

7.9.2.4 Overall RSD of the results of each analyst shall not differ by more than 15.0 %.

7.10 Dissolution / Release Rate

7.10.1 The dissolution test shall be carried out by both the analyst at receiving laboratory on six units of the sample of each lot.

7.10.2 **Acceptance criteria for Immediate release**

7.10.2.1 The RSD of six results obtained in each laboratory shall be compared as mentioned in the above table.

7.10.2.2 Overall RSD of the results obtained in each laboratory shall also be compared as mentioned in the above table.

7.10.3 **Acceptance criteria for Delayed release**

7.10.3.1 The release at acid stage for delayed release dosage forms shall comply with the specifications at receiving laboratory by both analysts.

7.10.3.2 For the release at buffer stage for delayed release dosage forms, result obtained at each laboratory shall be compared as mentioned in the above table.

7.10.3.3 Overall RSD of both the analysts shall also be compared as mentioned in the above table.

7.10.4 **Acceptance criteria for Extended /Modified release**

7.10.4.1 The absolute difference in mean result of both the analysts obtained at receiving laboratory at final time point shall be compared as mentioned in the above table.

7.11 Identification

7.11.1 One analyst in each laboratory shall carry out the tests on same sample at receiving laboratory.

7.11.2 Where the identification test is based on the results of another test, the transfer shall be deemed complete with the transfer of that test e.g. Identification based on retention time in HPLC/ GC etc.

7.11.3 **Acceptance criteria**

7.11.3.1 The results of both analysts shall meet with the requirements stated in the product specifications.

7.12 Microbiological Testing (qualitative and quantitative limit tests)

7.12.1 Execute common on-site validation protocol in triplicate by the transferring laboratory and receiving laboratory. Use different lots for each validation exercise.

7.12.2 **Acceptance criteria**

7.12.2.1 Demonstrate recovery of microorganisms, recovery level should be with in acceptance limit specified in protocol or in specification by either the laboratory or analysts.

7.12.3 Drug substances and dosage form test shall be transferred as per below table.

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Dosage Form									
Tests	**Drug Substance**	**Solid**	**Parenteral**	**Semisolid**	**Liquid**	**Oral**	**Dry**	**Ophthalmic**	**Inhalation**
Assay	√	√	√	√	√	√	√	√	√
Content uniformity	NA	√	√	√	√	√	√	√	√
Related substance/ Impurity/ Degradants	√	√	√	√	√	√	√	√	√
Residual solvent	√	√	NA	√	NA	√	NA	NA	√
Dissolution	NA	√	NA	NA	NA	√	√	NA	NA
Identification	√	√	√	√	√	√	√	√	√
Preservative Assay	NA	NA	√	√	√	NA	NA	√	NA
Microbiological (MLT)	√	√	√	√	√	√	√	√	√

7.13 Concerned Head or designee of receiving laboratory shall instruct the analyst to perform method transfer for test.

7.14 Analyst of receiving and transferring laboratory shall perform testing as per approved STP and analytical method protocol given by transferring laboratory.

7.15 Analytical method transfer shall be completed within 15 days from the day it was started by both the laboratory of the same batch/ lot of sample.

7.16 Analyst shall compile the data and compare the result with certificate of analysis received from transferring laboratory or generate at the site as per acceptance criteria.

7.17 Analyst shall communicate any observations / discrepancies observed during method transfer to Head QC or designee and shall be mentioned in method transfer report.

7.18 Concerned Head or designee of receiving laboratory shall ensure the performance and correctness of result of method transfer.

7.19 Head or designee of receiving laboratory shall communicate the observations/discrepancies observed during method transfer with transferring laboratory vice versa and can make amendment after confirming with transferring laboratory or receiving laboratory in the method but not limited to following.

- Step up / step down in sample or standard preparation or mobile phase preparation.
- Addition of identification solutions.
- Filter compatibility
- Sonication time / temperature

- Centrifuge time and / or speed.
- Stability of solution

7.20 Based on observation / discrepancies, receiving laboratory shall revise the method and send the revised copy of method and justification if necessary to transferring laboratory.

7.21 If results of method transfer complies as per acceptance criteria then method transfer shall be considered as complete.

7.22 Receiving laboratory and transferring laboratory shall prepare a comparative summary method transfer report as per Attachment-IV which shall be approved by Receiving and transferring laboratory.

7.23 In case of non –compliance of acceptance criteria the analysis at both the end shall be investigated and concluded in the method transfer report.

7.24 In case of any failure, head or designee of receiving laboratory shall evaluate and decide further course of action and same shall be communicated to transferring laboratory.

7.25 Test Results and Reports

7.25.1 All analytical results shall be recorded on respective substance/ product data sheet/ protocol template.

7.25.2 Each Transferring and receiving laboratory shall compile the results obtained at the receiving laboratories.

7.25.3 Head QC and Head QA shall review the reported data and shall be approved by both the laboratories.

7.25.4 If the results do not meet the acceptance criteria, both the laboratories shall investigate reasons for the same and recommendations shall be made.

7.25.5 The actions and recommendations shall be implemented and the report shall be resubmitted for approval.

7.26 Analytical Method Transfer Certificate:

7.26.1 If the results of both the laboratories meet the stated acceptance criteria, the Transferring laboratory shall prepare analytical method Transfer certificate (Attachment -V) and release after approval.

7.26.2 The Transferring laboratory shall initiate analytical Method Transfer Certificate and the same shall be reviewed and approved by receiving laboratory Head QA and Head QC.

7.27 Analytical Method Transfer training Report

7.27.1 Analytical Method transfer training Certificate shall be prepared by Transferring laboratory analyst and approved by receiving laboratory Head QA and QC once analytical method is successfully transferred (Attachment –VI).

8.0 REVISION HISTORY

Version No.	00	Effective Date	
Details of revision: New SOP Prepared			

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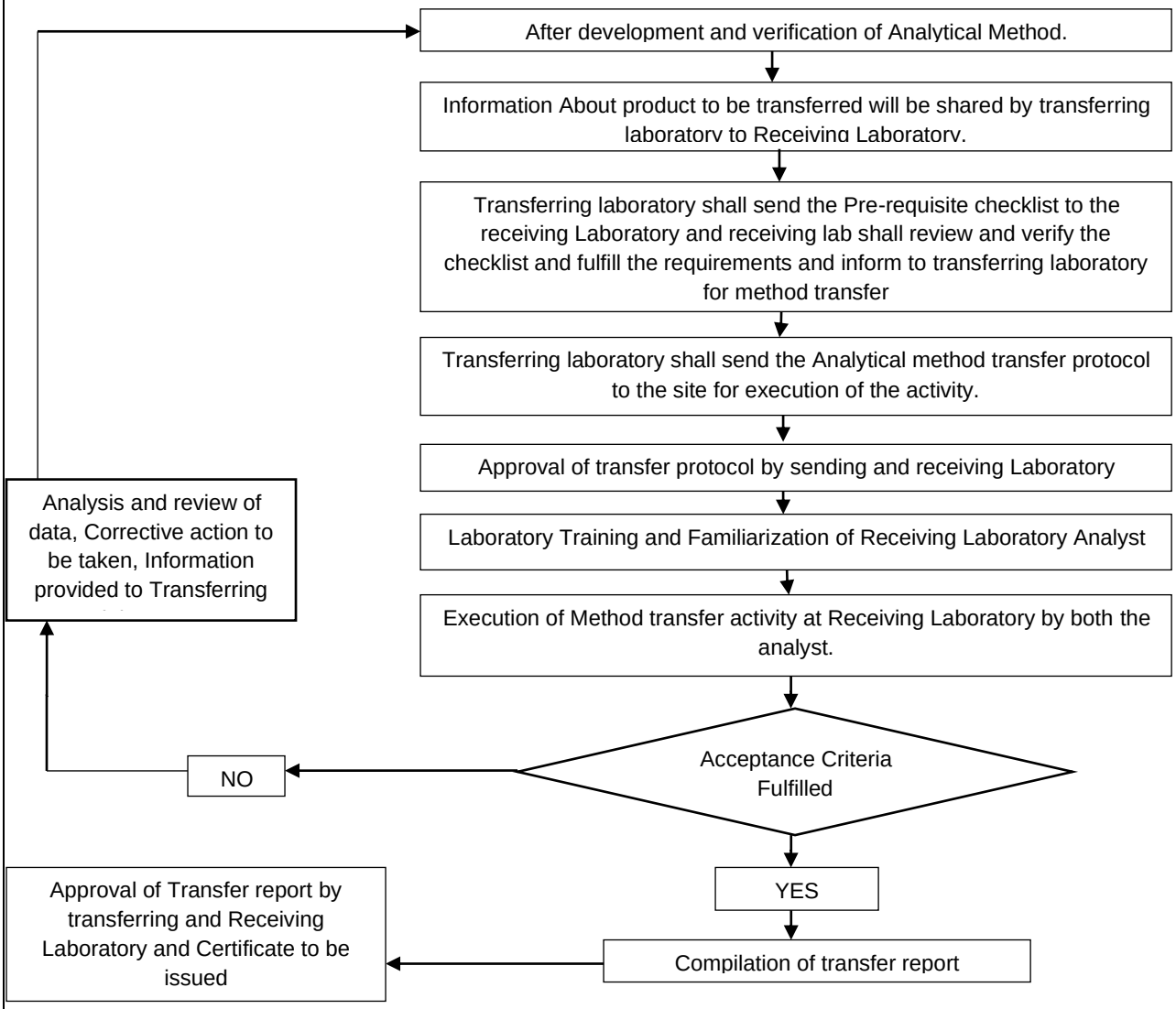
Attachment-I

Process Flow Chart for Analytical Method Transfer



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Attachment –II

Pre-requisite Checklist for Analytical Technology Transfer from Transferring Laboratory to Receiving Laboratory:

01)	**Instrument and Equipment with Make and Model**			
S.No.	Instruments Required Description	Make and Model	RL Comments	Remarks
a				
b				
c				
d				
02)	**Working reference standard/Impurities and API with pharmacopeia status**			
S.No.	Name	Pharmacopeia Status	Qty. Required	RL Comments	Remarks
a					
b					
03)	**Columns Description (Required for Tech Transfer)**			
S.No.	Columns Description	Make and Model	Qty. Required	RL Comments	Remarks
a					
b					
04)	**Reagents/ Chemicals Required With Grade and Make**			
S.No.	Name	Grade and Make	Qty. Required	RL Comments	Remarks
a					
b					
05)	**Sample/Placebo Requirement**			

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S.No.	Test Parameter	Qty. Required	RL Comments	Remarks
A				
B				

06) Documentation

S.No.	Document Name	Document No.	RL Comments	Remarks
a	Specification (RM, Excipients, In-process, FP)			
b	STP (RM, Excipients, In-process, FP)			
c	Method Transfer Protocol			
d	AMV Protocol/Report			

07	**General Requirements:**
	Solvent Required : grade
	Reagents and chemicals: grade
	Instrument Status: Instrument calibration data
	Filters:
	Class A Glass wares
	Milli Q water
08.	**Any Other Requirement**

Prepared By (Transferring Lab)

Sign/Date

Verified by (Receiving Lab)

Sign/Date

Format No……

Attachment- III

ANALYTICAL METHOD TRANSFER PROTOCOL

	ANALYTICAL METHOD TRANSFER PROTOCOL		
Product Name:		**Product Code**	
Doc No.:		**Revision No.:**	
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ANALYTICAL METHOD TRANSFER

PROTOCOL

FOR

Product Category: Drug Product/ Drug Substances

Product Name: _____

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Approval page Protocol:

This protocol has been developed and the individuals listed below have prepared and reviewed the document and agree with its content and with their signature grant approval for its execution.

Prepared By: Transferring Lab			
	Name	**Signature**	**Sign/ Date**
Reviewed By: Transferring Lab			
	Name	**Signature**	**Sign/ Date**
Approved By: Transferring Lab			
	Name	**Signature**	**Sign/ Date**
Approved By: Receiving Lab			
	Name	**Signature**	**Sign/ Date**
Approved By: Receiving Lab			
	Name	**Signature**	**Sign/ Date**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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1.0 **Objective:** The objective of this protocol is to describe the procedure and to transfer the technology for Analytical Method of Drug substance or Drug product by the Transferring laboratory to the QC Laboratory of receiving laboratory of ……..

2.0 **Scope:** This protocol is applicable for the transfer of Analytical method from transferring laboratory to receiving laboratory for product _____.

- To give better understanding to RL analysts for regular usage of methods.
- For analyzing the samples related to drug substance/ product (s) to be manufactured at site under supervision of transferring laboratory representative.

3.0 **Product Information:**

Product Category: Drug product/ Drug Substances

Name of Product: _____

Method Reference:

Type of Transfer:

4.0 **Details of Transferring Laboratory and Receiving Laboratory:**

- **Transferring Laboratory:**

Analytical development Lab, R&D.

The methods shall be received by the manufacturing facility of the dosage form.

- **Receiving Laboratory:**

Site address: …….

5.0 **Responsibilities:** This section comprising of a representative from each of the following department shall be responsible for the overall compliance of this protocol.

5.1 **Transferring Laboratory**

- To prepare, review and approval of the protocol.
- Timely completion of the Analytical Method Transfer.
- Successful transfer of the Analytical Method Transfer.

5.2 **Receiving Laboratory**

- Responsible to review, and approve the protocol.
- Analysis as per methods given in technical package by transferring laboratory under supervision of transferring laboratory representative.
- Timely completion of Analytical Method Transfer.

5.3 **Quality Assurance of Receiving Laboratory:**

- Responsible to verify and approval of the Analytical Method Transfer protocol.
- Co-ordinate with RL and transferring laboratory to carry out analytical method transfer.

6.0 Reference Documents:

Following documents are referred for analytical method evaluation/verification. (List of reference documents to be provided by transferring laboratory).

7.0 Reason for Transfer:

Reason for transfer to be mentioned by the transferring laboratory.

8.0 Comparative list of Instrument/ Equipment/ Reagents:

S.No.	R&D/Transferring Laboratory	Receiving laboratory	Remarks

9.0 Details of Analyst involved in testing:

10.0 Training Details:

Trainer Name		**Date of Training**	
Topic		**Location/ Place**	
Sr. No.	**Name of Trainees**		**Signature/ Date**
Remarks			

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11.0 Procedure:

11.1 The analytical method development lab of transferring laboratory shall be responsible for the preparation and issue of the protocol including the inputs/ requirements received by the receiving laboratory.

11.2 In the event that any questions arise during the exercise, the receiving laboratory shall contact the transfer coordinator for guidance.

11.3 The transferring and receiving laboratories shall be responsible to review all data they generate in their laboratory that is associated with the analytical method transfer exercise (AMTE) to ensure its accuracy and conformance with the requirements of this transfer plan before submission to the transfer coordinator.

11.4 Original documents such as workbook, raw data and concerned documents shall be maintained by the receiving laboratory and copies of the same shall be retained at transferring laboratory.

- The receiving laboratory shall be responsible to provide supporting information to the transfer coordinator.
- The analysts from transferring and receiving laboratories shall be responsible for preparation of the standard and sample, experimental work of the analysis and interpreting the results.
- If the receiving laboratory discovers that a questionable result is obtained during the transfer testing, questionable result shall be investigated as per their current local procedure (s) i.e. standard operating procedure(s). The receiving laboratory shall advise the transfer coordinator for the investigation.
- If an assignable cause cannot be determined for the questionable result, the receiving laboratory shall invalidate the data and repeat the testing.
- The receiving laboratory shall submit signed documentation detailing the investigation with the final transfer data.
- If an assignable cause cannot be determined, the receiving laboratory shall notify the transfer coordinator.
- If any of the acceptance criteria is not met, an investigation shall take place. Based on outcome of the investigation, the transfer coordinator and the source laboratory shall assess the impact and determine what, if any contingency testing is required.
- The Head QC from the receiving laboratory shall be responsible for ensuring the completion of this analytical method transfer at the receiving laboratory.

- The analyst A from transferring laboratory shall be responsible for the training of analyst from receiving laboratory on the analytical methodology, critical parameters and any precautions thereof.
- A qualification report shall be issued to the receiving laboratory upon successful completion and documentation of the transfer.
- The entire exercise of the analytical method handover shall be initiated after approval of the protocol.
- The start date and finish date of the actual method transfer at the receiving laboratory shall be documented during the transfer.

- Standard recording practices at the receiving laboratory shall be followed for recording the details of the analysis. Original raw data such as lab workbook chromatograms, printouts of equipments signed by the respective analyst shall be enclosed as annexure to the method transfer report and shall be archived in the receiving laboratory. Transferring laboratory shall retain copies of all the raw data of the method transfer exercise.

12.0 List of Specifications: Write the details as given below:

S.No.	Name of the Material	Category	Specification No.	STP No.
1.				
2.				

13.0 List of Working Reference Standards: Write the details as given below:

S.No.	Chemical/ Reagents	Source	Batch No./ Lot No.	Potency (%)
1.				

14.0 Details of sample (Drug substance/ Product)

S.No.	Drug substance/Product Name	Lot No./ Batch No.	Source
1.			

Testing to be performed by both the analysts at the receiving laboratory for the critical parameters.

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NOTE:

A comprehensive report of analytical method transfer with the details of the experimental work, results and interpretations of the data shall be prepared in one single report by both the analysts. The results must comply with the set acceptance criteria. The relevant cross references, primary raw data and instrument print outs are to be duly signed and filed as an Annexure to the method transfer report. The report shall be signed by both the analysts A and B and approved by the Head QC/ designee at the receiving laboratory.

15.0 Critical parameters Methodology and acceptance criteria:

S.No.	Test	Critical (C)	Methodology	Acceptance Criteria
1.	**Assay by HPLC**			
2.	**Dissolution by HPLC**			
3.	**Residual Solvents by GC**			
4.	**Related Substances by HPLC**			
5.	**Any other Test**			

16.0 Details of Deviation:

_____

_____

_____

_____

17.0 Corrective Action:

_____

_____

_____

18.0 Abbreviation:

19.0 Summary and Conclusion:

_____

_____

_____

_____

Attachment –IV

ANALYTICAL METHOD TRANSFER REPORT

	ANALYTICAL METHOD TRANSFER REPORT		
Product Name:		**Product Code**	
Doc No.:		**Revision No.:**	
Effective Date:		**Page No.**	

ANALYTICAL METHOD TRANSFER

REPORT

FOR

Product Category: Drug Product/ Drug Substances

Product Name: _____

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Report Approval Page:

This report has been developed and the individuals listed below have prepared and reviewed the document and agree with its content and with their signature grant approval for its execution.

Prepared By: Transferring Lab/ Receiving Lab			
	Name	**Signature**	**Sign/ Date**
Reviewed By: Transferring Lab			
	Name	**Signature**	**Sign/ Date**
Approved By: Transferring Lab			
	Name	**Signature**	**Sign/ Date**
Approved By: QA of Receiving Lab			
	Name	**Signature**	**Sign/ Date**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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1.0 Objective:

Analytical technology transfer to be prepared for a product specific method developed in Transferring Laboratory which needs to be transferred to a RL.

2.0 Scope:

This report shall be applicable for the compilation of result obtained during the transfer of Analytical Method from TL to RL give better understanding to analysts for regular usage of methods for analyzing the samples related to drug substance/product (s) to be manufactured at site under supervision of TL representative.

3.0 Product Details:

Product Category: Drug product/ Drug Substances

Name of Product: _____

Method Reference:

Type of Transfer:

4.0 Facility and Site of Study:

Transferring Laboratory

Analytical Development Lab.

The methods shall be received by the manufacturing facility of the dosage form.

Receiving Laboratory

Site Address:……..

5.0 Responsibilities: This section comprising of a representative from each of the following department shall be responsible for the overall compliance of this protocol.

5.1 **Transferring Laboratory**

- Responsible to prepare, review and approval of the report.
- Timely completion of the Analytical Method Transfer.
- Successful transfer of the Analytical Method Transfer.

5.2 **Receiving Laboratory**

- Responsible to prepare, review, and approve the report.
- Timely completion of Analytical Method Transfer.

5.3**Quality Assurance of Receiving Laboratory:**

- Responsible to verify and approval of the Analytical Method Transfer report.
- Co-ordinate with RL and transferring laboratory to carry out analytical method transfer report.

S.No.	Method Transfer Initiation Date	Method Transfer Completion Date
1.		

6.0List of Specifications: Write the details as given below:

S.No.	Name of the Material	Category	Specification No.	STP No.
1.				
2.				
3.				

7.0List of Working Reference Standards: Write the details as given below:

S. No.	Chemical/ Reagents	Source	Batch No./ Lot No.	Potency (%)
1.				
2.				

8.0 Details of sample (Drug substance/ Product)

S. No.	Drug substance/ Product Name	Lot No./ Batch No.	Source
1.			

9.0 Training Record: Provide details of Receiving laboratory and Transferring laboratory.

Trainer Name		Date of Training	
Topic		**Location/ Place**	
S. No.	**Name of Trainees**		**Signature/ Date**
Remarks			

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10.0 (a) Details of Joint/ collaborative study planned:

S. No.	Test	Observation	Specification Limit	Analyzed by Transferring Lab. Result	Analyzed by Receiving Lab. Result
1.					
2.					
3.					
4.					
5.					
% RSD (Each analyst)					
Overall % RSD					
Conclusion					

Note- Study plan to be prepared as per specific test and acceptance criteria.

Note: Analytical method shall be transferred by single batch analysis.

Testing to be performed by the analysts of both, the laboratories at the receiving laboratory for the above critical parameters.

11.0 Details of Deviation:

_____

_____

_____

_____

12.0 Corrective Action:

_____

_____

_____

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13.0 Conclusion:

_____

_____

_____

_____

Write based on study. **(Attach separate Report sheet wherever required)**

14.0 Attachment:

14.1 Format of Analytical method transfer approval certificate

14.2 Format of Analytical method transfer training certificate

15.0 Document Required:

S. No.	List of Documents Transferred to QC/QA	Received By	Sign/ Date
1.	In-Process Specification		
2.	Product Release Specifications		
3.	Finished Product Specifications		
4.	Test procedure for finished product		
5.	R & D COA for Finished Product		
6.	R & D COA for Working reference standards		
7.	Any other		

Format No……..

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Attachment –V

Analytical Method Transfer –Approval Certificate

We here by conclude that the following analytical test procedure is successfully transferred on dated _____to _____location based on the results obtained. The product reference test procedure details of tests transferred are below.

Name of Product: ***Batch No./Lot No.***

STP No. (Transferring Laboratory) ***Specification No.***

Test:

Prepared By (Transferring Laboratory)

Sign

Date

Approved By (Head QA/QC- Receiving Laboratory)

Sign

Date

Format No……

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Attachment –VI

Analytical Method Transfer Training Certificate

Transfer Analytical Method of Product/Material:

Date of Training :

STP and Specification No. (Transferring Laboratory)

Transferring Laboratory Analyst Name :

Receiving Laboratory Analyst Name :

Location (Transferring Laboratory)

Location (Receiving Laboratory)

Precaution and experimental tips explained to receiving laboratory Analyst (if any)

Details of specific recommendations (if, any)

Prepared By (Transferring Laboratory)

Sign

Date

Approved By (Head QA/QC- Receiving Laboratory)

Sign

Date

Format No……