TRANSPORT VALIDATION PROTOCOL

TRANSPORT VALIDATION PROTOCOL

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

TRANSPORT VALIDATION PROTOCOL

1.0 CONTENTS

TRANSPORT VALIDATION PROTOCOL

2.0 PROTOCOL PRE-APPROVAL:

Signing of this Pre-approval page of Transport Validation Protocol indicates agreement with the process approach described in this protocol. This protocol of Transport Validation has been prepared, reviewed, approved and authorized by the following persons for execution.

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
Sr. EXECUTIVE/ASSISTANT MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

TRANSPORT VALIDATION PROTOCOL

OBJECTIVE:

The objective of the Transport Validation Protocol is to summarize the philosophy, intentions and approach to perform validation activities in accordance WHO-TRS 961. The Transport Validation shall ensure that qualifications are done efficiently and consistently throughout the organization policy and meet regulatory, quality and business requirements.

3.0 SCOPE:

The scope of this protocol describes the steps to be taken to carry out temperature mapping of the specified Product from Start to Destination point with data logging frequency of 30 minutes. Transport Validation in such a manner that transport temperatures meet local regulatory requirements at the sending and receiving sites and/or so that temperature excursions above or below the manufacturer's labeled storage temperature range do not adversely affect product quality. Product stability data must demonstrate the acceptable temperature excursion time during transport

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following Departments,

Shall be responsible for the overall compliance of this Protocol

Department	Responsibility
Quality Assurance	**A)** Shall prepare & Review the Transport Validation protocol as per the Regulatory guideline. **B)** Execution of the Transport Validation protocol with FG department: verification of components calibration records of instrument, **C)** Verification of test & results. **D)** Shall compile the data & prepare summary report. **E)** Protocol shall be approved by the QA prior and after the execution. **F)** Shall review the executed protocol to check the compliance and corrective action for any discrepancies found. Also shall prepare the summary and conclusion of the study
Engineering	**A)** Responsible for trouble shooting (if occurred during execution). **B)** To affix recording instruments/sensors and then monitoring of the area under study at different locations/levels.
FG Store	**A)** Support Validation team for Transport Validation Activity.
Quality Control	**A)** Reviewing of Transport Validation protocol for correctness, completeness and technical excellence. **B)** Analyzed the Transport Validation Samples.

TRANSPORT VALIDATION PROTOCOL

5.0 TRAINING:

Provide the training to a team for the execution of protocol before execution of the transport validation and data shall be recorded.

6.0 LIST OF INSTRUMENT:

During Transport validation Data Logger used for Temperature mapping, that should be calibrated and Validity of data logger shall be valid.

7.0 PROCEDURE:

To ensure that the Product can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

8.1 When pharmaceutical products are stored at manufacturing sites or medical shops, it is recommended to maintain the controlled environment then it is also important to transit these products in specified controlled conditions.

8.2 Increase temperature can reduce the efficiency of the drug products. Transportation of these items has risk of temperature variation due to different factors; therefore it is required to validate the whole transportation process.

8.2.1 The Head QA shall decide the product for Transport Validation activity. After approval from Head QA, QA officer/Executive with FG Store Officer/Executive shall ready all the related documents.

8.2.2 FG Officer call for Transporter. Transport practices comply with all relevant local legislation and Regulations.

8.2.3 QA officer/Executive select the Product Shippers and Put the Calibrated Data loggers, in side it and packed properly and affixed the label on shippers **'SHIPPER WITH DATA LOGGER'** and same shall be recorded in BPR also.

8.2.4 FG officer/Executive shall kept this shipper in four corner and center define in figure No. 1 of the Vehicles. Vehicles should be properly locked; Vehicle driver should be trained for handling the data loggers during transit. Vehicle Drivers are informed about the perishability of the product and the maximum acceptable transport time.

8.2.5 This protocol describes the steps to be taken to carry out temperature mapping of the specified Product from Start to Destination point with data logger frequency of 30 minutes.

8.2.6 Risk assessment for different factors during transport as failure of data loggers, vibration, delay

during transit and other factors that can happen during the transit, should be done.

8.2.7 The samples required for Analysis shall be collected from destination point (selected shippers) and same shall be documented.

8.2.8 The Reconciliation of the Transport Validation Product shall be reported in Report. Transit Route and Transit time shall be recorded in Validation Report.

8.2.9 All the Validation Batches Details Shall be recorded in Validation Report.

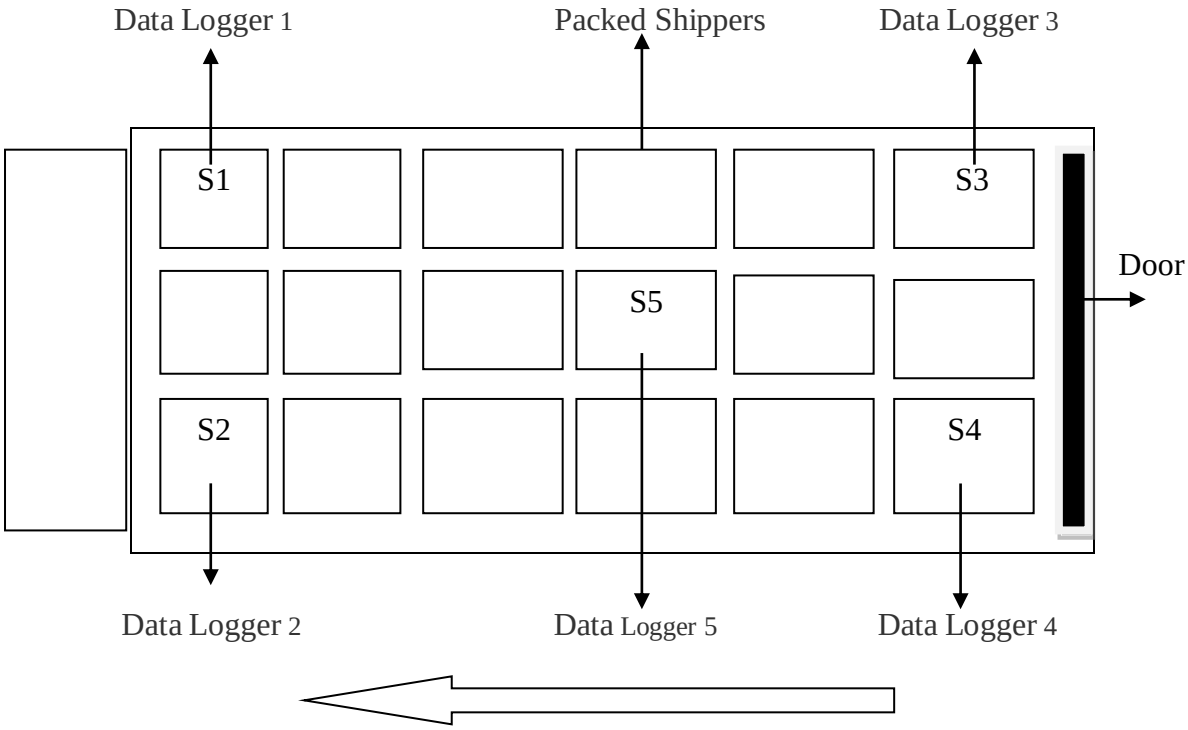

Fig. No. 1

Location of Data Loggers:

S.No.	LOCATION FOR Data Logger	Data Logger No.
1.	Right Corner of Vehicle	S1
2.	Left Corner of Vehicle	S2
3.	Near Main Entry Door (Right)	S3
4.	Near Main Entry Door (Left)	S4
5.	Middle of Vehicle	S5

TRANSPORT VALIDATION PROTOCOL

8.0 ACCEPTANCE CRITERIA:

The temperature of the Finished Product shall be not more than defined storage condition (as per the Specified in Batch Manufacturing and Batch Packing Record). The Validation samples of Finished Product shall be tested as per the latest version of Finished Product Specification.

9.0 DEVIATION (If Any):

During Transport validation of define Product any deviation occurred, shall be investigate and to be addressed in Transport Validation report.

10.0 CHANGE CONTROL (If Any):

During Transport validation of define Product any changes occurred, shall be investigate and to be addressed in Transport Validation report.

11.0 DOCUMENTS TO BE ATTACHED:

During Transport validation of define Product validation related documents shall be attached for the reference purpose.

12.0 CONCLUSION:

A summary report shall be prepared to summarise the results of the Validation Studies. On the basis of evaluation of results, a conclusion shall be drawn to state the transport validation.

13.0 RECOMMENDATION

After completion of Transport Validation activity if any recommendation suggest by the Validation team shall be recoded in Transport Validation Report.

TRANSPORT VALIDATION PROTOCOL

14.0 ABBREVIATIONS:

S. No.	Abbreviated Form	Full Extended Form
1.	TVP	Transport Validation Protocol
2.	WHO-TRS	World Health Organization-Technical Report Series
3.	QA	Quality Assurance
4.	QC	Quality Control
5.	RA	Regulatory Affair
6.	FG	Finished Goods
7.	QA	Quality Assurance
8.	QC	Quality Control
9.	RA	Regulatory Affaire
10.	°C	Degree Celsius
11.	Sign	Signature
12.	No.	Number