TRANSPORT VALIDATION REPORT

TRANSPORT VALIDATION REPORT FOR

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TRANSPORT VALIDATION REPORT

1.0 CONTENTS

PHARMA DEVILS

QUALITY DEPARTMENT

TRANSPORT VALIDATION REPORT

1.0 REPORT PRE-APPROVAL:

Signing of this Pre-approval page of Transport Validation Report indicates agreement with the process approach described in this Report. This Report 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
EXECUTIVE/ASSISTANT MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

TRANSPORT VALIDATION REPORT

2.0 Objective:

The objective of the Transport Validation Report 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 Report 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 Report.

Department	Responsibility
Quality Assurance	**A)** Shall prepare & Review the Transport Validation Report as per the Regulatory guideline. **B)** Execution of the Transport Validation Report with FG department: verification of components calibration records of instrument, **C)** Verification of test & results. **D)** Shall compile the data & prepare summary report. **E)** Report 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.

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5. PROCESS MONITORING

The Validation process were studied/monitored and documented in the report as per the details given in protocol. The details are documented as:

TABLE- I - TRAINING DETAILS
TABLE- II - LIST OF INSTRUMENNT
TABLE- III - BATCH DETAILS
TABLE- IV - TRANSPORT VALIDATION ROUTE
TABLE- V - SAMPLING LOCATION
TABLE- VI - TRANSPORT VALIDATION REPORT
TABLE- VII - ANALYTICAL RESULTS
TABLE- VIII - RECONCILATION

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TABLE I: TRAINING DETAILS:

Name of Trainer(s): **Designation:**

Date of Training : **Duration:**

S.No.	Name of Trainee	Department	Signature

Comments (If any):

_____

_____

_____

Training given by

_____ _____ _____

Name **Sign** **Date**

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TABLE II : LIST OF INSTRUMENT:

The Instrument (Data Logger) used for Temperature mapping shall be calibrated.

Instrument Name	Instrument ID	Date of Calibration	Due Date of Calibration	Calibration Certificate No.	Checked By QA

TABLE III: BATCH DETAILS

S. No.	BATCH NO.	MFG DATE	EXP DATE	BATCH SIZE
1.				
2.				
3.				

TABLE IV: TRANSPORT VALIDATION ROUTE

The Vehicle shall be moved on fixed route by Validation team and define Time:

Batch No.	Transporter Name	Start Point	Destination Point	Start Point Time	Destination Point Time	Checked By QA

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TABLE V: SAMPLING LOCATION

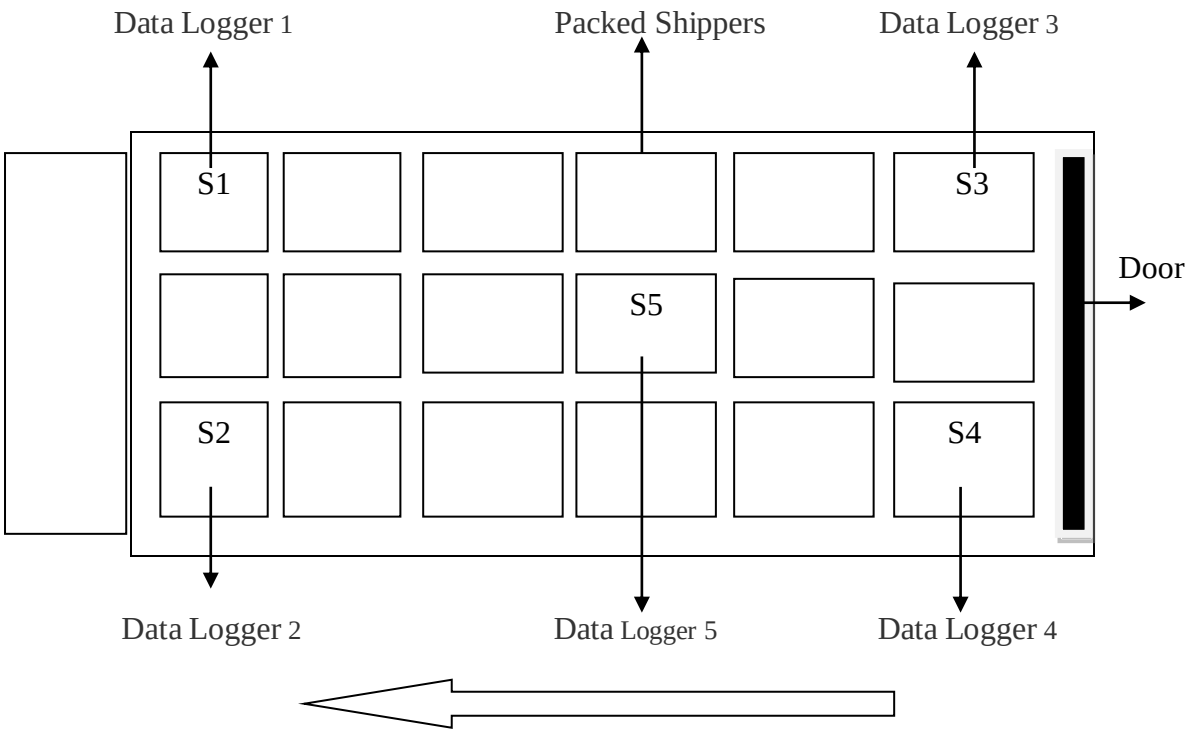

Fig. No. 1

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

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TABLE VI: TRANSPORT VALIDATION REPORT

Record the temperature observed during the Validation temperature monitoring in the record as mentioned.

Temperature monitoring Record (NMT 30°C)									
Minimum Temperature					**Maximum Temperature**				
S1	S2	S3	S4	S5	S1	S2	S3	S4	S5
Batch No.									
Batch No.									
Batch No.									
Verified by QA									

Temperature Monitoring Record (Annexure – I, Annexure – II and Annexure - III) of the ..... Batches attached with this Report.

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TABLE VII: ANALYTICAL RESULTS:

The Validation samples area tested in QC as per updated Finished Product Specification and summarised below:

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TABLE VIII: RECONCILIATION:

S.No.	Parameter	Details to be recorded		
		Batch No.	Batch No.	Batch No.
1	Date of Transport Validation Start Date			
2	Quantity of Finished Product dispatched from Warehouse			
3	Quantity/Available Stock of Finished Product at warehouse			
4	Quantity damaged /loss during transit			
5	Sample withdrawn s for Testing			
6	Variation in Quantity: {(2) – [(3) +(4)+(5)]}			
7	Transport Validation end date			
8	Total Time required (Transport Validation start time to Transport Validation end time)			

6.0 ACCEPTANCE CRITERIA:

The temperature of the ……shall be not more than 30°C of storage. The Validation samples of Finished Product shall be tested as per the latest version No. ……. of Finished Product Specification No. ……...

7.0 DEVIATION (If Any):

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8.0 CHANGE CONTROL (If Any):

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9.0 DOCUMENTS TO BE ATTACHED:

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10.0 CONCLUSION:

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11.0 RECOMMENDATION

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12.0 ABBREVIATIONS:

S. No.	Abbreviated Form	Full Extended Form
1.	TVR	Transport Validation Report
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.	°C	Degree Celsius
10.	Sr.	Serial
11.	No.	Number

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5.0 POST APPROVAL:

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			