TRANSPORT VALIDATION STUDY FOR THE SHIPMENTOF THE PRODUCTS FROM .....FACILITY TO WAREHOUSE FACILITIES IN ABROAD

ROUTE OF TRANSPORTATION: ROAD - SEA

TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

APPROVAL

Signing the Transportation verification study approval section indicates agreement with the methodology and requirements for transportation testing requirements of shipping products from ..... location to warehouse facilities in ..... via combination of Road and Sea routes.

_____

Prepared By: Quality Assurance
(Name, Signature & Date)

_____

Reviewed By: Quality Assurance
(Name, Signature & Date)

_____

Reviewed By: Warehouse
(Name, Signature & Date)

_____

Reviewed By: Production
(Name, Signature & Date)

_____

Approved By: Quality assurance Manager
(Name, Signature & Date)

_____

Authorized By: Site Head
(Name, Signature & Date)

_____

Authorized By: Contract giver
(Name, Signature & Date)

TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

ABBREVIATIONS USED IN THIS DOCUMENT

GMP	Good Manufacturing Practice
SOP	Standard Operating procedures
QA	Quality Assurance
LTD	Limited
RM	Raw materials
PM	Packaging Materials
GDP	Good Documentation Practice
QC	Quality Control

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TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

INTRODUCTION:

All products manufactured in..... and exported to ..... shall be subjected to transport verification study as defined in this document. ..... is committed to comply with GDP by ensuring that all its products are verified through proper transport process verification. This is an important part of the overall site Quality Management process to demonstrate the products are produced consistently in compliance with GMP & GDP. The temperature will be monitored during shipping to ensure that the shipment is not exposed to extreme conditions which could compromise the quality and efficacy of the products.

OBJECTIVE:

The objective of this study is collection & evaluation of data to establish that by using correct distribution practices the products will not be exposed to temperature outside the required storage conditions as demonstrated by stability data.

SCOPE:

The scope of this study is limited to one transportation verification run for products manufactured in ..... and exported to ..... for customer **.....** by road & sea route to cover the temperature mapping during its transit from India to warehouse facilities in.....

This study is applicable for single shipment (1st shipment) verification run as initial transport validation study with three continuous runs through specified route of transportation (Road & Sea) is already performed (other customer with same route).

Trails can be performed on batches intended for commercial use.

The verification trial involves including temperature monitoring through 9 locations (data logger placed in such way it cover all the area) within a load. Upon completion of this study all loads will be routinely monitored from at least 2 locations within the load (As per customer recommendation after verification study in 1st shipment).

Shipping condition may not exceed 25^{o}C as per product requirement.

TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

TRANSPORT STUDY RATIONALE:

It is intended that all products are transported in temperature controlled containers. The temperature and humidity (if required) will be monitored during shipping to ensure the material is not exposed to extreme condition which could compromise the quality and efficacy of the product. The product will test before shipping and after shipping in order to determine if there is any changes physical &/or chemical Characteristics of the product (as per FG test specification) as a result of different transport method as well as to provide a comparison of results for such product that are subjected to transport conditions. This study will generate data to demonstrate the effectiveness of this control across the load. Upon completion of this study routine monitoring will ensure that control is maintained. The conditions will be within the range that is demonstrated as acceptable by stability studies. Thereby providing assurance that the efficacy, quality and safety of the product is unaffected by its transportation.

RESPONSIBILITIES:

1) ..... Operations – Responsible for production and packaging of shipments planned for this transportation verification study

2) ..... Quality control – Responsible for analysis of products pre-shipment and Generate test report.

3) Site Warehouse –Responsible for executing the transportation study and communication of information to shipment receipt at destination country and Quality.

4) Shipping receipt at Abroad Warehouse –To remove the data loggers from Shipment, download and transfer information to Quality team at .....

5) Abroad Quality control – Responsible for analysis of the received products upon receipt and report.

6) ..... Quality Assurance – Responsible for placing data loggers into shipments, executing the transportation study & to review the uploaded information, deal with excursions using the standard response in Annexure - 4 & any incident as per Annexure-3. Ensure appropriate conclusions are drawn from the data to meet the objectives of this study, finalise the closeout report.

7) QA –Abroad – To review and approve study protocol and the final report.

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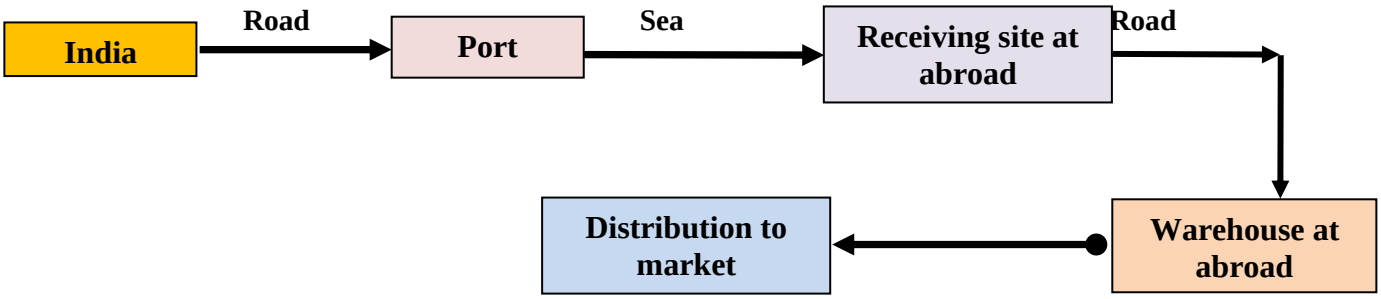
TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

MODE OF TRANSPORT:

Includes Road → Air or Sea-→ Road shipments.

TRANSPORTATION "MAP''



TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

PROCESS STEPS:

Step No.	Action	Responsibility
1.	➢ To ensure that the products are produced with approved materials. ➢ To produce shipments planned for this transportation study.	Site - Production
2.	➢ To ensure that all RM and PM is tested as per specs and released for production. ➢ To complete analysis of finished products pre-shipment and generate testing report.	Site – Quality control
3.	➢ To check and ensure the storage condition of cargos/container during transportation from respective product requirements. ➢ To ensure that the data loggers are calibrated before insertion into the shipments. ➢ To follow the SOP for Handling of temperature data loggers QA. ➢ Place the data loggers in container at defined locations as per Annexure-5. ➢ To record data logger details at the time of dispatch on the data sheet annexure-2 of this document. ➢ Communicate the details to all concerned after shipping.	QA & warehouse - Site
4.	➢ Upon receiving the shipment in Abroad the information from data loggers should be downloaded and forward reports to Quality assurance, Site. ➢ Post shipment detail shall be recorded as per Annexure-II.	Shipment receipt at destination country.
5.	➢ Post shipment analysis and reporting	Abroad Quality
6.	➢ To oversee execution of this transportation study. ➢ To review the uploaded information & deal with excursions if any using the standard response in Annex 4. ➢ Ensure appropriate conclusions are drawn from the data. ➢ To meet the objectives of this study, finalise the closeout report. ➢ Finalise the study, draw conclusions and recommendations for future.	Site - QA

TRANSPORT VALIDATION STUDY FOR THE SHIPMENT OF THE PRODUCTS FROM ..... FACILITY TO WAREHOUSE FACILITIES IN.....

TRANSPORTATION STUDY METHODOLOGY:

Calibrated data loggers shall be used for temperature monitoring during transportation verification study. The data loggers named as “Log Tag”, model “USRIC – 16” single used temperature recorders shall be used for temperature monitoring. For example/ to describe the methodology, handling procedure for “Log Tag USRIC – 16 single used temperature recorders” is described below:

The USRIC-16 is a single use USB temperature recorder that can be directly plugged into the computer for configuration and generation of PDF reports. Configuring and evaluating the data generated by the USRIC-16 requires installation of LogTag Analyzer software version 3.1.1.

Log Tag Analyzer software installation:

Download & install the software on your computer using/ clicking the given link. Save the ‘ltanalyzer_25r16.exe’ file on your computer in desired destination folder.

Installing the USRIC-16

Step 1: Start the Log tag Analyzer software.

Step 2: Remove protective cap on the USRIC-16 and insert into USB port on computer. The device drivers will be installed on your computer.

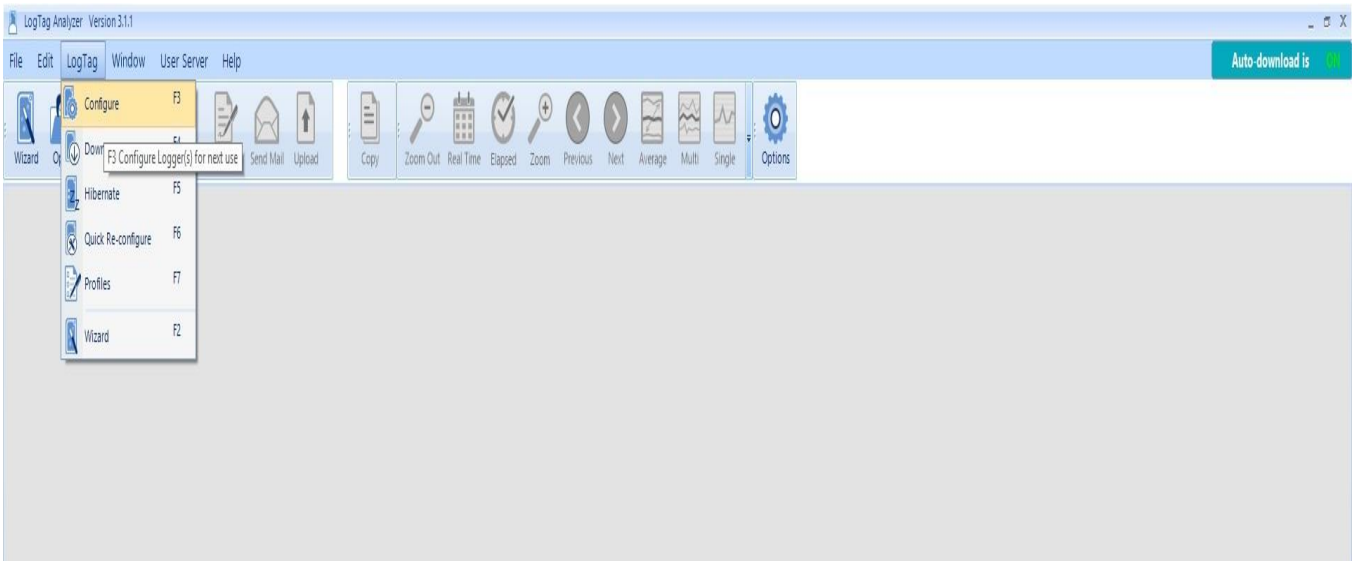
Step 3: Click ‘Close’. The USRIC-16 is now ready for configuration, using Log Tag Analyzer

USRIC-16 Configuration

Note: USRIC-16 configuration possible only after installation of the Log tag Analyzer.

Note: Do not unplug the USRIC-16 from the computer during configuration

1. Open the Log Tag Analyzer software. Click ‘LogTag’ and choose ‘Configure’



2. The following window opens with various configuration options. File setting & Advanced options are also available for customization

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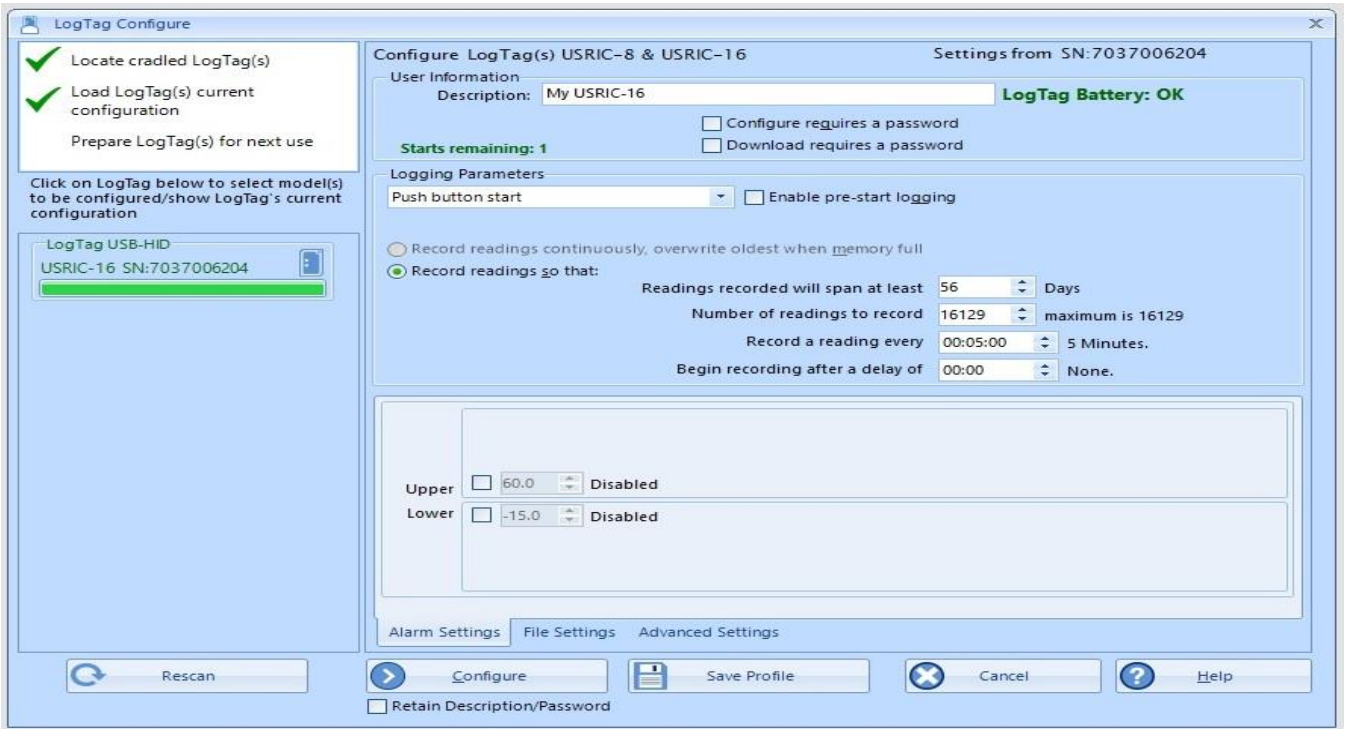
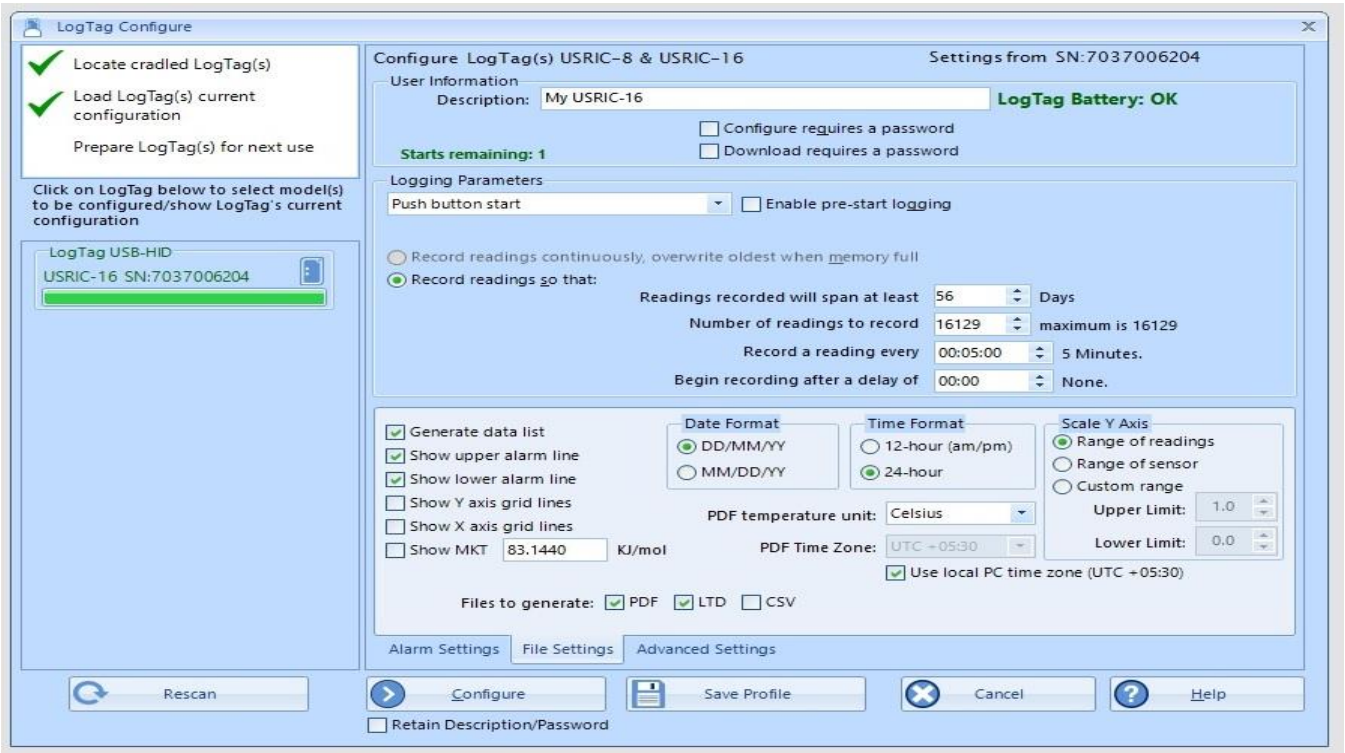
Configuration panel



Advanced Configuration panel



Enter the desired options to accept the new values.

This returns you to the standard configuration dialogue.

3. Click ‘Configure’ to upload configuration data to USRIC-16. Remove device from USB hub and replace

protective cap.

Starting the USRIC-16:

Using the configuration options, users can decide when the device starts recording temperature.

- via Push button start: Press the START/MARK button to start recording temperature immediately. When pre-start logging is enabled USRIC-16 starts recording as soon as it is unplugged from the USB port and the device continues to record data till the START/MARK is pressed. This way you do not lose readings even if you forget to start the unit.

- via Date/Time start: Using this option the USRIC-16 can be configured to record temperature readings at the date and time (local time) specified by user.

Data Retrieval from USRIC-16:

If you have used the 'File/Advanced setting' during configuration to Generate files, then files (pdf/ltd/csv) will be created every time you plug the recorder into the USB port.

1. Plug USRIC-16 in to USB port on computer.
2. The device will appear as a new mass storage device with the USRIC-16 serial number as the device name.
3. Open the mass storage device to view files.
4. PDF files can be views using PDF viewer, LTD files need Log Tag Analyzer software and CVS files can be imported to spreadsheet program like MS ExcelTM
5. The files are not automatically stored in your computer and need to be manually copied and pasted into file location of your choice.
6. The USRIC-16 can be unplugged directly and does not require specific procedure to stop or un mount the device.
7. Every time the device is plugged into the computer, the files are generated, this action ceases when the battery is exhausted.

Data Interpretation:

The data generated from the USRIC-16 appears as a chart or data list.

These data loggers shall be calibrated, with an internal memory and clock to record data every 5 /15 / 30 minute during transit. Temperature alarm will be enabled for quick identification if temperature exceeds the limits. Data loggers shall be placed in shipments.

Shipment upon arrival at the destination country shall be

- Visually inspected to ensure no damages & record the detail as per Annexure-I of QA SOP.
- Information from data loggers will be downloaded.
- Finish product subjected to standard release testing in Quality control lab at Abroad.

Results shall be compared with the initial release testing data to see if any variance is evident.

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ANALYSIS OF RESULTS:

The shipment will be tested before shipping and post shipping condition shall be verified in order to determine if there are any changes of the product as a result of the combination of road and sea shipment mode, to provide a comparison of the results that are subjected to transport conditions. The temperature will be monitored during shipping to ensure that the shipment is not exposed to extreme conditions which could compromise the quality and efficacy of the products.

Temperature mapping data will be reviewed by Site Quality Assurance which will be supported by the pre shipment and post shipment detail & temperature mapping reports. Any incident shall be raised as per the Annexure - 3 of this study protocol if necessary.

Upon completion of verification run, a separate final summary report shall be prepared, reviewed and approved by QA and all stake holders which shall demonstrate that transportation processes is verified.

ACCEPTANCE CRITERIA:

Data logger charts should be reviewed for shipment by Site QA.

- Shipments are clearly acceptable in case of No damage of corners & faces, No sign of any water soaking, No smudging of labels or label peel off.
- Shipments are clearly acceptable if temperature is not exceeding 25^0 C during its transit from Baddi to destination countries. However exception of +/- 2^0C to above said (27^0C) for less than 24 hrs is also acceptable. If the temperature excursion is greater than 24 hrs outside of 27^0C then deviation should be raised and investigated.
- In case of any excursion in temperature, QA should review the post shipment analysis report against the stability data of the product and raise product disposition statement as per annexure 4 of this protocol before disposition for further distribution or disposal of product is made.

TRANSPORTATION STUDY CONSIDERATIONS:

1. Product must be shipped in good conditions (No damage condition)
2. Products must be transported in the agreed manner for that product. In all cases temperature controlled transport (containers) is required.
3. Products before shipping should be verified by analytical testing and should comply with our release specifications.
4. Post shipment detail shall be verified & should comply with pre shipping condition.
5. Product shall be monitored by using calibrated data loggers which will be capable of monitoring Temperature during its full journey.
6. Finally all data captured during this study will be analysed and presented in the final report.

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REPORT AND APPROVALS:

Separate summary report shall be prepared for verification run based on the findings of this transportation verification study. The report will summarize the results and review of the documentation. All the filled Annexure shall be attached with report. The transportation study summary report will indicate the status of the transportation via container shipping freight of products from Site to warehouse in Abroad.

LIST OF ATTACHMENTS:

The attachments used in this study will be used to document the results of the transport study.

Annexure 1: Signature log

Annexure 2: Shipment/Dispatch detail

Annexure 3: Transportation study incident form

Annexure 4: Product disposition statement

Annexure 5: Data logger placement diagram

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ANNEXURE 1- SIGNATURE LOG

Objective of this document is to record details of all personal involved in the execution of this transportation verification study. Individuals should record their name, sign, department and Initials/date in the table below. Signatories indicate that they have read and understand this transport study and their assumed responsibilities.

Name	Signature	Department	Initials / date

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ANNEXURE 2 - SHIPMENT/DISPATCH DETAIL			
Following detail shall be recorded at the time of dispatch:			
Container No.		**Container size**	
Market		**No. of shipper loaded**	
No. of Data loggers placed		**Set Logging time**	
Date of dispatch		**Date (Data logger placed)**	

PRODUCT DETAIL			
S.No.	**Product Name**	**Batch No.**	**Recommended storage conditions**

Physical condition of container (Should be integral without any damage & perforations)	

Checked By (Sign & date)		**Verified By (Sign & date)**	

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ANNEXURE 2 - SHIPMENT/DISPATCH DETAIL (Cont.)

Data logger shall place in such way that it covers all the area, within a load as per location diagram.

Following detail shall be recorded at the time of dispatch:

Data logger ID./Sr No.	Calibration status	Location	Shipper No.

Checked By (Sign & Date)		Verified By (Sign & Date)	

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ANNEXURE 3- TRANSPORTATION STUDY INCIDENT FORM		
Incident No:	**Batch No.:**	**Date:**
Description of Incident:		
Impact on Quality of product:		
Corrective actions taken (by/date)		
Preventative actions if any:		
Completed Product disposition statement as per Annexure 5 attached (Required)		

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Documented by: _____ Date: _____

Reviewed by: _____ Date: _____

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Annexure 4: PRODUCT DISPOSITION STATEMENT

The following temperature excursion information has been received from _____ date _____

Product Information:

Products:

Batch (es):

Expiry date:

Country of deliver:

Temp tale numbers:

Delivery Number(s):

Temperature data:

Minimum temperature from Temp tale data:

Maximum temperature from Temp tale data:

Time in hours above allowable upper limit (27^0C for less/more than 24 hours):

Based on the stability data available, it has been concluded that the product has been adversely affected/ not affected by the temperature excursion mentioned above.

Decision: The above mentioned batch (es) should be released /not released for further distribution.

Name: _____ **Position:** _____

Signed:_____ **Date:** _____

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Annexure 5: Data Logger Placement location Diagram

Data logger shall be placed as in required quantity & record the location as below mentioned diagram