TRANSIT STUDY PROTOCOL CUM REPORT

FOR

FINISHED GOODS

TRANSIT STUDY PROTOCOL CUM REPORT

REVISION HISTORY

Rev.	Date	Authorized By:	Revision Summary
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TRANSIT STUDY PROTOCOL CUM REPORT

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1.0 Pre-Approval Sheet:

Prepared By (Name & Designation)	Signature	Date
(Quality Assurance)		

Checked By (Name & Designation)	Signature	Date
(Production)		
(Quality Control)		
(Warehouse)		
(Engineering)		

Approved By (Name & Designation)	Signature	Date
(Quality Assurance)		

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2.0 Objective:

To delineate a procedure for monitoring the temperature during transportation of finished goods from …….. to Overseas Customers.

3.0 Scope:

This procedure is applicable to all finished products (dosage forms) dispatched from …….. to various overseas customers.

4.0 Responsibility

Quality Assurance:

QA is also responsible for preparation and checking and ensuring execution of protocol cum report, and verification of proper conducting transit studies,

Warehouse: To provide simulated packs for conducting transit studies and Review of summary report

5.0 Execution Plan :

Initiation Date : _____

Completion Date: _____

6.0 Methodology:

6.1 Head QA shall choose the consignment for conducting transit studies. Theconsignment shall consist of minimum one approved batch to be dispatched.

6.2 Head QA shall intimate Head - Warehouse that QA intends to do transitstudies.

6.3 Head–Warehouse shall revert to Head QA with details of product, batchnumber and customer details of an appropriate consignment meetingrequirements.

6.4 Accordingly Head QA shall intimate Warehouse toarrange and include one simulated packs in the consignment with unit packs (containing equal to twicethe quantity required for analysis).

6.5 Manager QA shall place data logger in the simulated pack; which is a red coloured box. The box is affixed to the shipper using green coloured adhesive tape for easy identification.

PLEASE RETURN THIS PACK TO THE FOLLOWINGADDRESS

……

6.6 Head QA shall intimate through a letter to customer to return the abovesimulated pack immediately after receipt of the consignment. Head QA also request Customer to provide the details of consignment receipt.

6.7 After receipt of the consignment back in factory, Head QA shall intimate QCto draw samples and perform assay and identification test as per the current finished product specifications. Head QA shall consider the transit periodbetween dispatch date and date of receipt of the consignment at customer'send.

6.8 Manager QA shall take out the data loggers from the received simulated bulk pack and intimate Engineering to download the data.

6.9 Head QA shall compare the results of transit study with previous results ofassay in batch release and identify any differences in results.

6.10 Head QA shall review the temperature and identify any large excursions in data.

7.0 Acceptance Criteria:

7.1 The containers are received back in good physical condition with no damage.

The temperature and moisture ingress into the packs recorded throughout the transportation shall be as below:

Temperature should be around 25°C &

Following excursion in the temperature shall be allowed:

Not more than 28°C for a period not exceeding 6 hours.

Not more than 30°C for a period not exceeding 3 hours.

8.0 Results & Observations:

Compile the results of batch analysis as Annexure – I (COA of Finished Good).

Compile the data of temperature as Annexure – II in the following format:

Date	Time	Temperature

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9.0 Deviations:

Record any deviations in study and evaluate their impact on the results.

10.0 Conclusions:

Evaluate the results and conclude impact of transit conditions on the quality of product along with the other samples that are received for Identification and Assay testing.

11.0 Re-qualification criteria:

Change in packaging configuration.

Change in the acceptance criteria.

Change in regulatory guidelines.

12.0 Summary & Conclusion:

Prepared By:
(Sign & Date)

Checked by:
(Sign & Date)

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13.0 Post Approval Sheet:

Executed By (Name & Designation)	Signature	Date
(Quality Assurance)		

Checked By (Name & Designation)	Signature	Date
(Production)		
(Quality Control)		
(Warehouse)		

Approved By (Name & Designation)	Signature	Date
(Quality Assurance)		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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TEMPERATURE MONITORING RECORD IN TRANSIT STUDY

Date	Time	Temperature