

# Pharmaceutical Transport Validation Checklist

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## Initial Planning & Risk Assessment

Assessment of transport risks and development of validation plan.

### Project Scope Definition

Write something...

### Product(s) Included in Validation

- Active Pharmaceutical Ingredient (API)
- Finished Dosage Form
- Intermediate Product



### Number of Batches to be Validated

Enter a number...

### Planned Start Date of Validation

Enter date...

### Potential Risks Associated with Transport

Write something...

### Transport Mode(s) Considered

- Road
- Air
- Sea
- Rail

### Acceptance Criteria for Temperature Excursions (Celsius)

Enter a number...

# Packaging System Evaluation

Review of packaging materials and design for product protection.

## Packaging Material Description

Write something...

## Package Weight (kg)

Enter a number...

## Primary Packaging Material

- Glass
- Plastic
- Aluminum
- Cardboard

## Secondary Packaging Material

- Cardboard
- Plastic Wrap
- Pallet

### Package Features

- Insulated
- Vacuum Sealed
- Shock Resistant
- Temperature Controlled

### Packaging Material Certificate of Analysis

 Upload File

### Rationale for Packaging Material Selection

Write something...

## Temperature Monitoring Equipment Qualification

Verification of data loggers and temperature sensors accuracy and reliability.

### Data Logger Serial Number

Enter a number...

### Temperature Sensor Calibration Point 1 (°C)

Enter a number...

### Temperature Sensor Calibration Point 2 (°C)

Enter a number...

### Temperature Sensor Calibration Point 3 (°C)

Enter a number...

### Calibration Standard Used

- NIST Traceable Standard
- Certified Reference Material
- Other (Specify)

### Detailed Calibration Procedure

Write something...

### Calibration Completion Date

Enter date...

### Calibration Start Time

### Calibrator Signature

## Simulated Transport Runs (Phase 1)

Controlled simulations of transport conditions to establish baseline performance.

### Start Date of Simulation

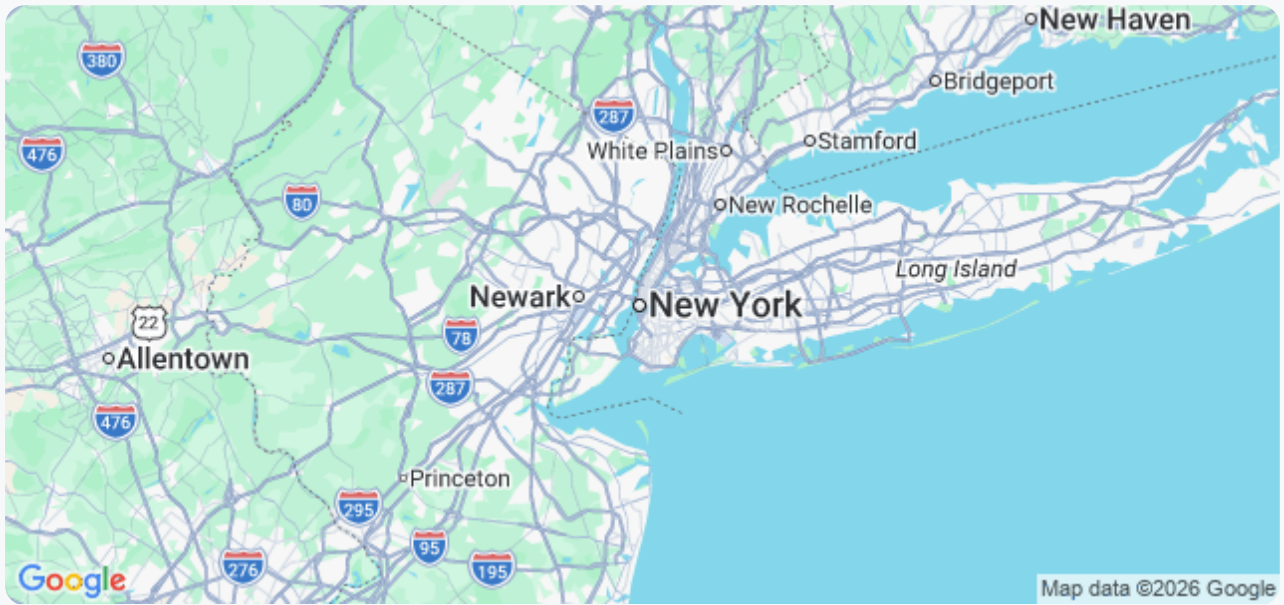
### Simulation Start Time

### Ambient Temperature (°C)

## Product Temperature (°C)

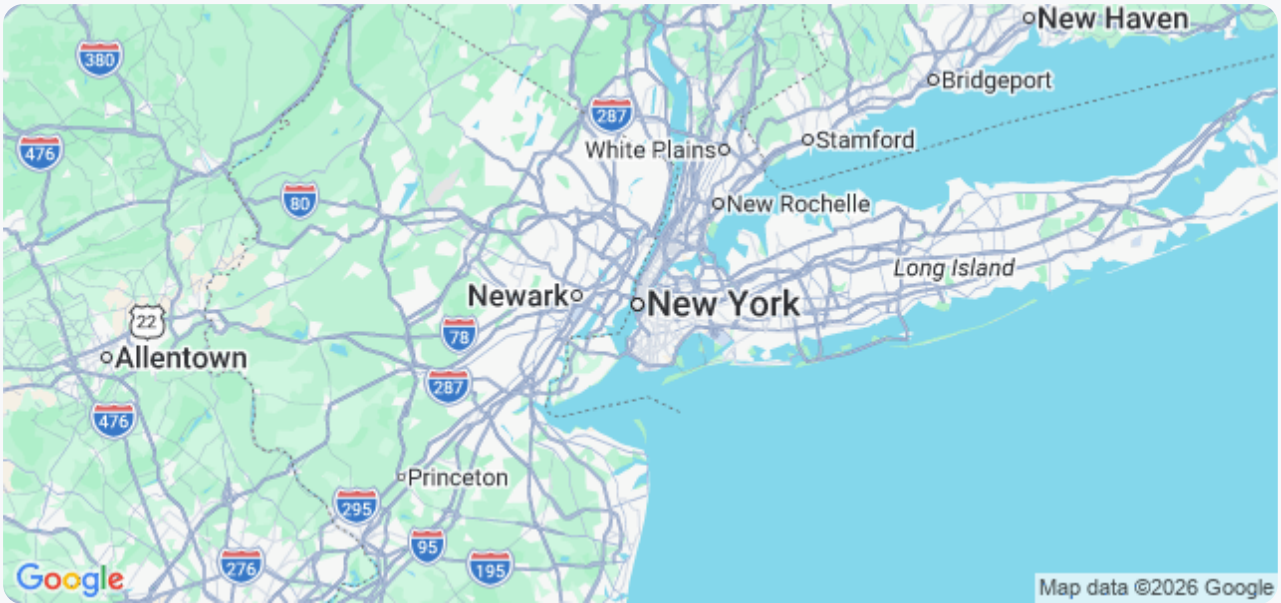
## Origin Location

 [Set My Current Location](#)



## Destination Location

 Set My Current Location



## Transport Mode

- Truck
- Air
- Sea
- Courier

## Duration of Simulation (Hours)

Enter a number...

# Simulated Transport Runs (Phase 2) - Deviation Scenarios

Simulations incorporating potential deviations (e.g., delays, temperature excursions).

## Deviation Type

- Temperature Excursion
- Delay in Transit
- Mechanical Shock
- Vibration
- Humidity
- Other (Specify)

## Duration of Excursion (minutes)

## Temperature Excursion Magnitude (°C)

## Start Date of Delay

### Start Time of Delay

Enter time...

### Delay Duration (hours)

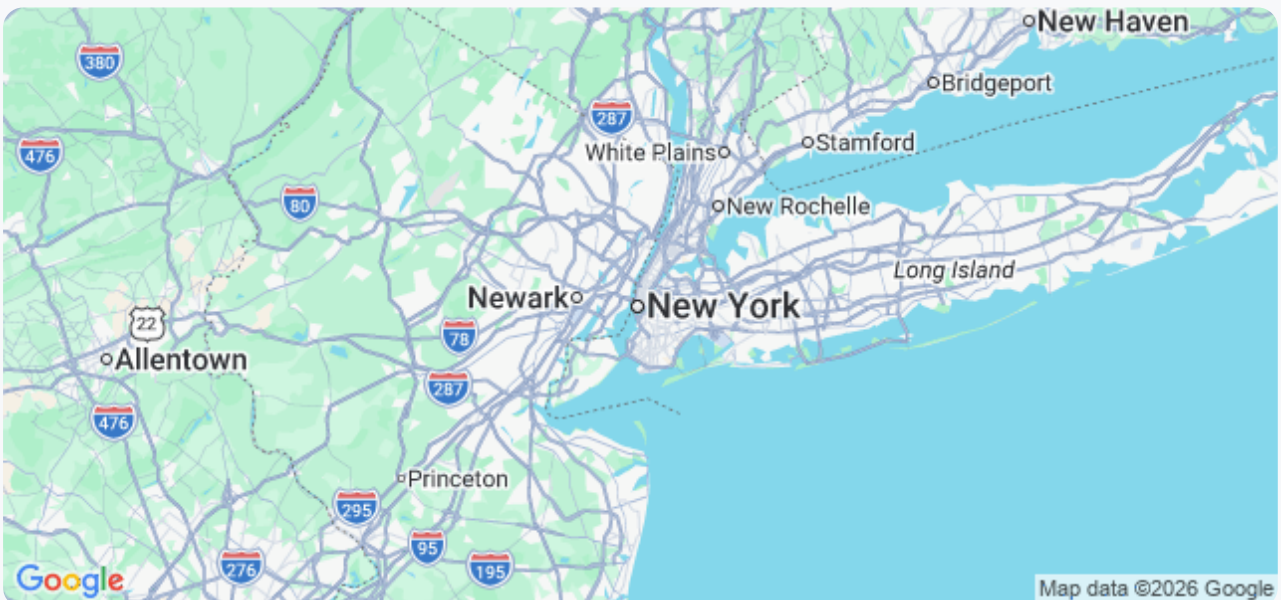
Enter a number...

### Description of Deviation

Write something...

### Location of Deviation Event

 [Set My Current Location](#)



# Data Analysis & Reporting

Review of temperature data and generation of validation report.

## Minimum Acceptable Temperature (°C)

Enter a number...

## Maximum Acceptable Temperature (°C)

Enter a number...

## Number of Excursions

Enter a number...

## Summary of Temperature Excursions (if any)

Write something...

## Overall Validation Status

- Pass
- Fail
- Conditional Pass

### Date of Analysis Completion

### Raw Data Files (CSV, Excel)

 Upload File

### Analyst Signature

## Corrective Actions & Verification

Implementation of corrective actions and verification of effectiveness.

### Description of Corrective Action(s) Implemented

### Quantity of affected product/materials

### Date Corrective Action(s) Were Completed

Enter date...

### Impact on Product Quality

- No Impact
- Minor Impact
- Significant Impact

### Root Cause(s) Addressed

- Packaging Failure
- Temperature Control Issues
- Documentation Errors
- Personnel Training

### Signature of Responsible Person (Verification)

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## Periodic Review & Revalidation

Schedule for periodic review and revalidation of the transport validation.

### Last Revalidation Date

Enter date...

### Revalidation Cycle Frequency (in months)

Enter a number...

### Summary of Review Findings

Write something...

### Overall Validation Status

- Valid
- Requires Minor Updates
- Requires Major Revalidation

### Justification for Validation Status (if not 'Valid')

Write something...

### Next Scheduled Revalidation Date

Enter date...

### Reviewer Signature

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