SOP title	Temperature excursion management		
SOP No.		Version	
Effective date		Review date	
Department		Site	

1. Purpose

To assess and decide on products exposed to temperatures outside their labelled range.

2. Scope

Excursions in storage, receipt or transport at _____.

3. Responsibilities

Person who detects the excursion reports it; QA investigates and decides product disposition.

4. Definitions

5. Procedure

1. Immediately protect the product: move it to correct storage and quarantine it. Do not discard anything yet.
2. Report the excursion to QA within [1] hour using Form CC-05.
3. Record: unit, products and batches affected, start and end time, minimum or maximum temperature, and total duration outside range.
4. Download and attach the full temperature record.
5. QA assesses the impact using the manufacturer's stability data or excursion guidance. Contact the manufacturer where needed.
6. Check freeze-sensitive products for freezing, including a shake test where applicable and validated.
7. QA decides disposition: release, release with restrictions, or reject.
8. Raise a deviation and investigate root cause.
9. Raise CAPA to prevent recurrence and set an effectiveness check.
10. Notify customers or the marketing authorisation holder where product already dispatched may be affected.

Decision flow

Step	Question	If yes	If no
1	Was the product outside its labelled range?	Go to step 2	No excursion; record alarm only
2	Is stability data available for this exposure?	Go to step 3	Contact manufacturer; keep quarantined
3	Is the exposure within the stability allowance?	Release with QA approval; record	Reject and destroy per SOP
4	For freeze-sensitive products, was the product frozen?	Reject	Continue assessment

6. Records

Form CC-05 Excursion report; deviation; CAPA; disposition decision.

7. References

8. Revision history

Version	Date	What changed and why	Changed by

9. Approval

	Name & designation	Signature	Date
Prepared by			
Reviewed by			
Approved by (QA)			

> Sample template. Replace bracketed text with your own details, align it with your product labels, and have QA approve it before use.