

PLEASE COMPLETE THE FOLLOWING AND SUBMIT ALONG WITH SAMPLE. One sample per form ONLY.

STABILITY PRODUCT TESTING SUBMISSION FORM

PRODUCT NAME:

SAMPLE SIZE:

LOT/FORMULA No.:

PO/Ref. No:

PRODUCT CATEGORY: ☐ OTC ☐ COSMETIC ☐ NUTRITIONAL ☐ MEDICAL DEVICE ☐ Rx ☐ STORAGE ☐ OTHER:

PRODUCT TYPE: ☐ RAW MATERIAL ☐ BULK/IN PROCESS ☐ FINISHED GOOD

Packaging Material:

Semi-permeable container? ☐ Yes ☐ No

Quantity of Sample's Submitted:

SPECIAL HANDLING:

Active Ingredient(s)/ Preservative(s)	Amount (%)	Active Ingredient(s)/ Preservative(s)	Amount (%)	Active Ingredient(s)/ Preservative(s)	Amount (%)	Active Ingredient(s)/ Preservative(s)	Amount (%)

Stability Test Requirements

*After the final pull date, products are Stored for three (3) months prior to disposal. *

STABILITY PROJECT INTERVAL(S) (in months)

Accelerated: ☐ INITIAL ☐ 1 ☐ 2 ☐ 3 ☐ 6 ☐ 9 ☐ 12 ☐ Other: _____

Intermediate: ☐ INITIAL ☐ 1 ☐ 2 ☐ 3 ☐ 6 ☐ 9 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 36 ☐ 48 ☐ 60 ☐ Other: _____

Long Term: ☐ INITIAL ☐ 1 ☐ 2 ☐ 3 ☐ 6 ☐ 9 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 36 ☐ 48 ☐ 60 ☐ Other: _____

Organoleptic Identification Test

Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ Appearance:

☐ Color:

☐ Package/Product Incompatibility

☐ Odor:

Viscosity Determination Testing

Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ Specification Range:

☐ Time:

☐ Spindle Type:

☐ Speed:

pH Determination Testing

Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

Specification: ☐ Range:

☐ Report Results Only (RRO)

Specific Gravity Testing

Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

Specification: ☐ Range:

☐ Report Results Only (RRO)

☐ Weight-Loss Identification Test

Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

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☐ **POINT AFTER OPENING (PAO) Test** Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ **PHOTOSTABILITY TEST** Criteria / Specification (s): Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ **FREEZE-THAW TEST** Criteria / Specification (s): Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ **PRESERVATIVE CHALLENGE TEST** Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ **KILL RATE TEST** Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:

☐ **Bioburden Testing** Specification Intervals: ☐ All selected with the Stability PJT. Field ☐ Other:
☐ **Microbial Limits Testing** ☐ <100 ☐ Other:

NOTE: All samples will be stored at room temperature, unless special handling indicates otherwise. Method validations are the responsibility of the manufacturer for each product. ALL ANALYTICAL SAMPLES REQUIRE VALIDATION PER FDA REGULATIONS.

COMMENTS / CUSTOMER PROVIDED METHOD(S):

Customer
Release
Signature: _____ Date: _____

Customer
Witness
Signature: _____ Date: _____

REQUIRED FOR TESTING TO BE INITIATED

COMPANY:

COMPANY CONTACT:

PHONE:

EMAIL:

ADDRESS:

Please DO NOT write below — LAB USE ONLY

Stability Project No.

Sample(s) Received By
(initials) and Date:

Color:

Quantity of Sample(s)
Received:

State:

Entered to database
by (initials) / Date:

Clerical Review
by (initials) / Date:

Technical Review
by (initials) / Date: