



# EMSL ANALYTICAL, INC.

200 Route 130 North  
Cinnaminson, NJ 08077

Phone: (800) 220-3675 Fax: (856) 786-5973

## STABILITY FORM

Client Name: \_\_\_\_\_ Product Name: \_\_\_\_\_

Client Contact: \_\_\_\_\_ Phone Number: \_\_\_\_\_

### Determination of Expiration Date for Climate Zones I, II, III :

- \_\_\_ 1 year: Accelerated testing at 40°C and room temperature at 25°C for 1 year
- \_\_\_ 2 year: Accelerated testing at 40°C and room temperature 25°C for 2 years
- \_\_\_ 3 year: Accelerated testing at 40°C and room temperature 25°C for 3 years
- \_\_\_ Freeze/Thaw testing at 0°C for 7 Days for liquid products

### Optional Temperatures:

- \_\_\_ Accelerated testing at 30°C (if 40°C samples are not passing)
- \_\_\_ Climate Zone IVa testing 30<sup>0</sup> C; 65% RH
- \_\_\_ Climate Zone IVb testing 30<sup>0</sup> C; 75% RH
- \_\_\_ Climate Zone IV Accelerated Study at 40<sup>0</sup>C; 75% RH
- \_\_\_ Water Permeable Containers 30<sup>0</sup> C; 75% RH
- \_\_\_ Water Impermeable Containers 30<sup>0</sup> C; RH not specified

### Product Type:

- \_\_\_ Pilot, new production, or commitment batch. Circle one.
- \_\_\_ Retest of an existing product that had a previous stability study. Current shelf life \_\_\_\_.
- \_\_\_ Has suitability testing (bacteriostasis/fungistasis) been conducted previously? Yes No
- \_\_\_ Has there been an ingredient or process change since this initial suitability test? Yes No
- \_\_\_ Has preservative effectiveness (AET) been conducted previously? Yes No
- \_\_\_ Has there been an ingredient or process change since the first (AET) test? Yes No

### Product Matrix:

- |                 |                          |
|-----------------|--------------------------|
| ___ Aerosol     | ___ Liquid               |
| ___ Conditioner | ___ Oral suspensions     |
| ___ Capsules    | ___ Oral powders         |
| ___ Deodorant   | ___ Shampoo              |
| ___ Cream       | ___ Topical products     |
| ___ Lotion      | ___ Ophthalmic Product   |
| ___ Injection   | ___ Tablet               |
| ___ Lipstick    | ___ Other please explain |

Number of Lots to be tested: 1, 2, or 3

Lot #: \_\_\_\_\_

Final Package Type: \_\_\_\_\_

Final Package Size: \_\_\_\_\_



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Testing required at each interval:

- |                          |   |                          |                             |
|--------------------------|---|--------------------------|-----------------------------|
| <input type="checkbox"/> | Active Ingredient Assay (specify below) | <input type="checkbox"/> | Pathogens (specify below)   |
| <input type="checkbox"/> | AET (Preservative Effectiveness)        | <input type="checkbox"/> | Particulate matter          |
| <input type="checkbox"/> | BP Monograph Specify _____              | <input type="checkbox"/> | pH                          |
| <input type="checkbox"/> | Color, odor and appearance              | <input type="checkbox"/> | Pyrogenicity                |
| <input type="checkbox"/> | Consistency                             | <input type="checkbox"/> | Shape                       |
| <input type="checkbox"/> | Dissolution                             | <input type="checkbox"/> | Softening range             |
| <input type="checkbox"/> | FCC Monograph                           | <input type="checkbox"/> | Solids                      |
| <input type="checkbox"/> | Friability                              | <input type="checkbox"/> | Specific Gravity            |
| <input type="checkbox"/> | Hardness                                | <input type="checkbox"/> | Sterility                   |
| <input type="checkbox"/> | Homogeneity                             | <input type="checkbox"/> | USP Monograph Specify _____ |
| <input type="checkbox"/> | Identification                          | <input type="checkbox"/> | Viscosity                   |
| <input type="checkbox"/> | Microbial limits                        | <input type="checkbox"/> | Weight loss                 |
| <input type="checkbox"/> | Moisture                                |                          |                             |
| <input type="checkbox"/> | Package Appearance                      |                          |                             |

Other: \_\_\_\_\_

**Active Ingredients**

**% Claim**

**Active Ingredients**

**% Claim**

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Print Name

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Signature

\_\_\_\_\_  
Date