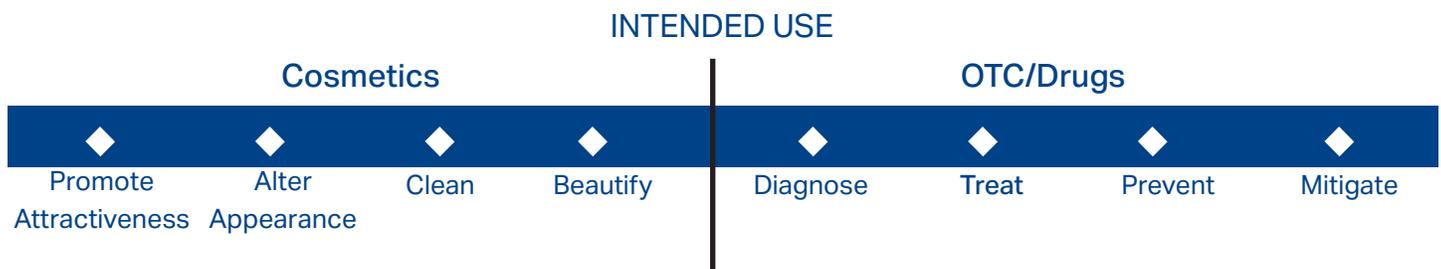# OTC/Cosmetic Stability Checklist

Purpose:

OTC/drug products are required to undergo stability testing per FDA regulations in the U.S., stability testing for cosmetic products is recommended.

Most Commonly Tested OTC Products

- Acne treatments
- Antibacterial/Antimicrobial creams and gel
- Antifungal creams and sprays
- Antiseptic hand sanitizers
- First aid ointments
- Foot sprays/powders

- Hydrocortisone creams and ointments
- Lip balms with actives
- Medicated mouthwashes or oral rinses
- Medicated shampoo
- Sunscreens
- Topical analgesics

INTENDED USE

Cosmetics				OTC/Drugs			
Promote Attractiveness	Alter Appearance	Clean	Beautify	Diagnose	Treat	Prevent	Mitigate

Step 1: Identify the Appropriate Regulations

Both cosmetics and OTC/drugs are regulated under the Food Drug & Cosmetic Act (FD&CA), and each product category has specific requirements under title 21 of the Federal Code of Regulations.

Regulations Affecting Cosmetic Products

▶ 21 CFR Parts 1, 2, 11, 20, 250, 700, 701, 710, 720, 740
▶ Modernization of Cosmetics Regulations Act (MoCRA)

Regulations Affecting OTC/Drug Products

▶ 21 CFR Parts 99, 110, 200, 201, 202, 210 211

Step 2: Establishing Shelf-Life (Required for OTC)

Shelf-life defines how long an OTC or cosmetic product remains safe, stable, and effective under recommended storage conditions. It's determined through stability studies that track product performance and quality over time.

Stability Study Setup

Designed under ICH Q1A(R2) and FDA guidelines, stability studies assess product quality at scheduled time points (e.g., 0, 3, 6, 9, 12, 24 months) under:

• Long-term: 25 °C / 60 % Relative Humidity
• Accelerated: 40 °C / 75 % Relative Humidity
• Custom temperatures available upon request

Parameters tested include physical appearance, assay, pH, microbial limits, preservative efficacy, active ingredients, and packaging integrity.

Recommended that the preservative system be tested at multiple timepoints throughout the stability study.

Determining Expiration

If the product remains within specification, an expiration date is assigned based on data trends. Examples include:

• 6 months: R&D studies
• 12 months: for pilot batches or temperature-sensitive creams
• 18–24 months: for most topical and oral OTCs
• 36 months or longer: for highly stable products (e.g., tablets, anhydrous ointments)

Storage Only Service

Store your samples at your desired temperature using our fully validated, ICH-compliant stability chambers.

Ready to talk to our testing experts for your stability project?

Contact A Stability Testing Expert
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