

Stability Testing Checklist

Is your stability file launch-ready?

Brand

Date

THE 4-TRACK STABILITY PLAN

- 1. Accelerated stability.** Heat-stressed samples checked for appearance, color, odor, viscosity, pH and packaging. About 3 months at PMG; supports the initial shelf-life claim.
- 2. Preservative challenge (USP <51>).** Five test organisms, held at 20–25°C for 28 days, sampled at 7, 14 and 28 days.
- 3. Packaging compatibility.** Does the formula react with the pump, tube or jar? For OTC drugs, testing in the marketed container-closure system is required.
- 4. Real-time confirmation.** Normal-condition samples checked until the full claimed shelf life, confirming (or shortening) the date.

LAUNCH-READY STABILITY CHECKLIST

- ☐ Final formula version locked (a formula change may mean retesting)
- ☐ Final package chosen and used for all stability samples
- ☐ Accelerated stability started; initial results reviewed
- ☐ Real-time stability started on the same batch, with a check-in schedule
- ☐ Preservative challenge test (USP <51> or PCPC method) passed
- ☐ Compatibility results for pump, tube or jar reviewed
- ☐ Shelf-life or expiration claim matches the data (and storage statement, for OTC)
- ☐ For OTC: written stability program in place; any tentative date flagged for confirmation
- ☐ For EU sales: date of minimum durability or period-after-opening symbol decided
- ☐ All reports saved in your safety substantiation / product file (you own the data)

Notes

SOURCES

FDA, Shelf Life and Expiration Dating of Cosmetics; FDA, MoCRA; 21 CFR 211.166 and 211.137 (eCFR); ICH Q1A(R2); EU Regulation 1223/2009; Certified Laboratories; CPT Labs (USP <51> vs PCPC)

General planning aid, not legal or regulatory advice. Confirm requirements with your manufacturer and regulatory reviewer.