

Pilot Batch Readiness Checklist

Complete before you book a pilot batch or first production run. Numbers in brackets refer to the sources below.

Brand / product

Date

FORMULA AND PACKAGE

- ☐ Formula approved in writing, with target specifications
- ☐ Final package, closure and label stock chosen and tested with the formula [1]

PILOT PLAN

- ☐ Purpose of the pilot written down: scale-up, stability, buyer samples, or all three
- ☐ Batch size agreed and documented, with who owns any leftover units [2]
- ☐ Decision made on whether units are sampling-only or intended for sale [2][3]
- ☐ Stability plan and testing lab agreed [1][4][8]

LABEL AND LAUNCH

- ☐ Label copy and claims reviewed for your category (cosmetic, supplement or OTC) [5]
- ☐ First production run quantity tied to a sell-through forecast or presales [6]
- ☐ Reorder lead time and pricing in writing

Notes

SOURCES

1. FDA / ICH, Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products (Nov 2003)
2. 21 CFR 111.205, master manufacturing record (dietary supplements)
3. 21 CFR 111.255, batch production record (dietary supplements)
4. 21 CFR 211.166, stability testing (drugs)
5. FDA, "Modernization of Cosmetics Regulation Act of 2022 (MoCRA)"
6. PMG, "Private Label vs Custom Formulation"
7. PMG, "Nutraceuticals & Supplements"
8. PMG, "Product Testing & Stability"

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