

TOPICAL LOTION/SUSPENSION

The following is a template to be used when drafting a Topical Lotion/Suspension monograph. This is intended to serve as a guideline for writing monographs in *USP* style. It is incumbent upon the monograph writer to be familiar with *USP General Notices* and the General Chapter tests. Note that not all tests would appear in any one monograph and that not every variation of individual tests is shown. Only those sections used most often are included. Tests are listed in the order in which they should appear in a monograph.

NOTES—See templates for Drug Substance, and Tablets and Capsules in the addendum of the *USP Guideline for Submitting Requests for Revision for USP–NF* for sections that are required but not included here, whether stated explicitly in the template or not.

Add the following:

[] **Topical Lotion/Suspension**

{ See template for Tablets for the sections not described here in details. }

>> [] Topical lotion/suspension contains not less than [xx.x] percent and not more than [yyy.y] percent of the labeled amount of [drug substance or active ingredient] [(C_xH_x___O_x)].

Packaging and storage—Preserve in [well-closed][tight][light-resistant] containers at [controlled room][between x° and y°] temperature.

Labeling—

{ The label states the name and quantity of each active ingredient and indicates its function (or purpose) in the article. }

{ See template for Tablets and Capsules in the addendum of the *USP Guideline for Submitting Requests for Revisions for USP–NF* for additional details. }

USP Reference standards <11>—*USP* [] *RS*. [*USP* [] *Related Compound* [] *RS*.]

Identification— { Need at least one ID test for each active ingredient. If more than one ID test is incorporated, tests have to be alphabetized, e.g., **A:**, **B:**, etc., and ordered as follows: IR, UV, TLC, retention times comparison, and other tests. See Tablets skeleton for reference. }

Microbial limits <61>—It meets the requirements of the tests for absence of [*Salmonella* species] [*Escherichia coli*] [*Staphylococcus aureus*] [*Pseudomonas aeruginosa*]. [The total aerobic microbial count does not exceed ___ per g, and the total combined molds and

yeasts count does not exceed ___ per g][the total aerobic microbial count is less than ___ per mL.] {If counting colony-forming unit(s), use cfu for singular or plural. }

Minimum fill <755>—meets the requirements.

pH <791>: between [] and [], [in a solution (___ in ___)].

Alcohol content[, *Method [I]/[II]* <611> [(if present)]: [between ___% and ___% is found][between ___% and ___% of the labeled amount of C₂H₅OH is found].

Residual solvents <467>: meets the requirements.

Impurity—

{Proceed as directed for Impurity tests under template for Tablets and Capsules in the addendum of the *USP Guideline for Submitting Requests for Revision for USP-NF*.}

Assay—

{Proceed as directed for Assay tests under template for Tablets and Capsules in the addendum of the *USP Guideline for Submitting Requests for Revision for USP-NF*.}