

## TRANSDERMAL DELIVERY SYSTEM

The following is a skeleton to be used when drafting a transdermal delivery system 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:*

### [\_\_\_\_\_] Transdermal System

>> [\_\_\_\_\_] Transdermal System contain not less than [90.0] percent and not more than [110.0] percent of the labeled amount of [drug substance or active ingredient] [(C<sub>x</sub>H<sub>x</sub>\_\_\_\_O<sub>x</sub>)].

**Packaging and storage**—Preserve in sealed [single-dose container][unit-dose pouch]. Store at [\_\_\_\_\_].

### **Labeling**—

The label states the total amount of [drug substance or active ingredient] in the Transdermal System and the release rate, [mg][μg] per day, for the duration of the application of one system. [Where more than one *Drug release* test is given in the monograph, the labeling states the *Drug release* test used only if *Test 1* is not used.]

**USP Reference standards** <11>—*USP* [\_\_\_\_\_] *RS*. [*USP* [Drug] *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. }

**Drug release** <724>—{If the monograph has more than one test, be sure to include a *Labeling* section except for Test 1 and use the following text: If the product complies with this test, the labeling indicates that it meets *USP Dissolution/Drug release Test* [x]. }

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[Test [1]:]

Medium: [\_\_\_\_]; [\_\_\_\_] mL.

Apparatus [5][6][7]: [ ] [rpm][cycles per minute]{ Provide necessary description of the test system including how the Transdermal System is held in place during testing. For Apparatus 7, provide the size of the solution container and indicate the sample holder that is used }

Times: [\_\_\_\_], [\_\_\_\_], [\_\_\_\_] hours.

Procedure—{ Describe if different from that in the chapter. } Determine the amount of  $[C_xH_xO_x]$  release by employing the following procedure. { Directions similar to those in the *Dissolution test* }.

Tolerances—The amount of  $C_xH_xO_x$  released, expressed as  $[\mu\text{g per hour per cm}^2]$  [a percentage of the labeled amount absorbed in in vivo], at the times specified, conforms to *Acceptance Table 1* for transdermal drug delivery systems.

<u>Time (hours)</u>	<u>[AMOUNT DISSOLVED]</u> <u>[RELEASE RATE]</u>
—	between — and —
—	between — and —
—	between — and —

**Uniformity of dosage units** <905>: meet the requirements for [*Weight Variation*][*Content Uniformity*].

**OR**

**Uniformity of dosage units** <905>: meet the requirements for *Weight Variation* with respect to [amoxicillin] and for *Content Uniformity* with respect to [clavulanic acid].

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

[Test solution— Transfer an accurately weighed portion of [Cream][Ointment], equivalent to about \_\_\_\_ mg of [active ingredient], to a \_\_\_\_-mL [volumetric flask][beaker][separator], [ ] { Insert the procedure for extraction. }

**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*. }

[Assay preparation— Remove the protective liners from the Transdermal Systems and transfer a number of Systems, equivalent to about \_\_\_\_ mg of [active ingredient], to a \_\_\_\_-mL [volumetric flask][beaker][separator], [ ] { Insert extraction procedure }