Status: Currently Official on 12-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: General Chapter
DocId: GUID-A2626350-169E-4D3E-8F8D-4CFDBA9A1E47_2_en-US
DOI: https://doi.org/10.31003/USPNF_M99400_02_01
DOI Ref: f7c9o

⟨641⟩ COMPLETENESS OF SOLUTION

Add the following:

▲The purpose of these methods is to verify that one or more materials are completely dissolved in a solution. These methods may be used to verify the descriptive solubility of a material according to the solubility table in *General Notices, 5.30 Description and Solubility*.

To verify the descriptive solubility, use the maximum amount of solvent specified for the descriptive solubility in the solubility table (see *General Notices, 5.30 Description and Solubility*). For example, for "soluble" use 30 parts of solvent. Into this amount of solvent, add 1 part of solute weighed accurately to 0.5%. Unless otherwise specified in the monograph, completeness of solution should be evaluated at 25°.

Evaluation of the completeness of solution, as described in this chapter, does not provide a precise measure of compound solubility. The descriptive solubility terms above should also not be confused with the terms "high solubility" and "low solubility" as applied to drug substances in the *Biopharmaceutical Classification System*.[1,2] For more information on precise solubility measurements and biorelevant solubility determinations, see *Solubility Measurements ⟨1236⟩*.

Unless otherwise directed in the individual monograph, use *Method I*.▲ (USP 1-Aug-2020)

Change to read:

▲METHOD I▲ (USP 1-AUG-2020)

Place the quantity of the substance specified in the individual monograph in a meticulously cleansed, glass-stoppered, 10-mL ▲color-comparison tube.▲ (USP 1-Aug-2020) Using the solvent that is specified in the monograph or on the label of the product, fill the ▲color-comparison tube to the 10-mL mark.▲ (USP 1-Aug-2020) Shake gently to dissolve: the solution is not less clear than an equal volume of the same solvent contained in a ▲matched color-comparison tube▲ (USP 1-Aug-2020) and examined similarly ▲(see *Visual Comparison ⟨630⟩, Viewing conditions for turbidity comparison*).▲ (USP 1-Aug-2020)

Add the following:

▲METHOD II

Place the quantity of the substance specified in the individual monograph into a meticulously cleansed 10-mL flask. Add 10 mL of the solvent that is specified in the monograph or on the label of the product. Shake gently to dissolve. Transfer the solution to a suitable measurement tube and measure the turbidity of the prepared solution per *Nephelometry and Turbidimetry ⟨855⟩*. The acceptance criterion is that the turbidity of the sample preparation is NMT that of *Reference suspension II* in *⟨855⟩*, *Table 1* [NMT 6 nephelometric turbidity units (NTU)].▲ (USP 1-Aug-2020)

1 US Food and Drug Administration. Guidance for industry. Waiver of in vivo bioavailability and bioequivalence studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. Rockville, MD: US Food and Drug Administration; December 2017.

2 USP. Reagents and Reference Tables, Solutions, Buffer Solutions, 4. Standard Buffer Solutions, 4.1 Preparation. In: *USP–NF*. Rockville, MD: USP; 1 May 2018.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
<641> COMPLETENESS OF SOLUTION	Antonio Hernandez-Cardoso Senior Scientific Liaison	GCPA2020 General Chapters - Physical Analysis 2020

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Current DocID: GUID-A2626350-169E-4D3E-8F8D-4CFDBA9A1E47_2_en-US

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