

Certificate

PARTICLE COUNT SET

USP Catalog No.:	1500502
USP Lot No.:	R050A0

The excerpt below is from USP-NF General Chapter <1788> Methods for the Determination of Particulate Matter/General Information

Particle Counting Accuracy—System Suitability

Determine the particle counting accuracy of the instrument, using *Method 1* (for sensors requiring the moving window half-count (MWHC) method for calibration), *Method 2* (for multichannel sensors), or *Method 3* for any instrument (manual comparison to membrane microscope method).

Method 1—MWHC Instruments

Procedure—Prepare the suspension and blank using the USP Particle Count RS. With the instrument set to count in the cumulative (total) mode, collect counts at settings of $\geq 10 \mu\text{m}$ and $\geq 15 \mu\text{m}$. Prepare the blank and suspension sample in the same manner. Degas the mixture by one of three means: by sonication (at 80–120 watts) for about 30 s, by allowing to stand, or by vacuum. Gently stir the contents by hand-swirling or by mechanical means, taking care not to introduce air bubbles or contamination. Stir continuously throughout the analysis. Withdraw three consecutive volumes directly from the container. Historically, these have been volumes of NLT 5 mL each, due to instrument limitations and the desire to maximize sample volume. However, where desired, volumes may be utilized that meet the standardization criteria and address the sensitivities of the formulation. Obtain the particle counts, and discard the data from the first portion. [NOTE—Complete the procedure within 5 min.] Repeat the procedure, using the suspension in place of the blank. From the averages of the counts resulting from the analysis of the two portions of the suspension at $\geq 10 \mu\text{m}$ and from the analysis of the two portions of the blank at $\geq 10 \mu\text{m}$, calculate the number of particles in each mL by the formula:

$$(P_S - P_B)/V$$

in which P_S is the average particle count obtained from the suspension; P_B is the average particle count obtained from the blank; and V is the average volume, in mL, of the 4 portions tested. Repeat the calculations, using the results obtained at the setting of NLT 15 μm .

Interpretation—The MWHC instrument meets the requirements for Particle Counting Accuracy if the count obtained at $\geq 10 \mu\text{m}$ and the ratio of the counts obtained at $\geq 10 \mu\text{m}$ to those obtained at $\geq 15 \mu\text{m}$ conform to the values that accompany the USP Particle Count RS. If the instrument does not meet the



requirements for Particle Counting Accuracy, and adequate test volumes remain, repeat the procedure with them; if insufficient volumes remain, prepare new suspension and blank, and then repeat the procedure. If the results of the second test are within the limits given above, the instrument meets the requirements of the test for Particle Counting Accuracy. If on the second attempt the system does not meet the requirements of the test, determine and correct the source of the failures, and retest the instrument.

LABEL TEXT

For use with specified USP compendia only.
Not for use as a drug. See SDS prior to use
at www.usp.org.

USP REFERENCE STANDARD

PARTICLE COUNT-BLANK 25 mL

Contains the aqueous phase without added particles.

Do not open until ready to begin test. Store in a refrigerator.

PROTECT FROM FREEZING

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666

Cat No. 1500502 LOT R050A0

Material mfd. in United States

For use with specified USP compendia only.
Not for use as a drug. See SDS prior to use
at www.usp.org.

USP REFERENCE STANDARD

PARTICLE COUNT-SUSPENSION 25 mL

Contains 15 µm polystyrene spheres in aqueous suspension.

Particles must be resuspended before use.

Do not open until ready to begin test. Store in a refrigerator.

PROTECT FROM FREEZING

Acceptance value: Counts at 10 µm: between 3350 and 4040 counts/ml

Ratio of counts at 10 µm to the counts at 15 µm: between 1.42 and 3.25

USP, 12601 Twinbrook Pkwy, Rockville, MD +1-301-881-0666

Cat No. 1500502 LOT R050A0 Material mfd. in United States

Jeri L. Joth

Quality Assurance

**Calculation Value**

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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