



USP REFERENCE STANDARD CERTIFICATE

PARTICLE COUNT SET

USP Catalog No.:	1500502
USP Lot No.:	R211H0

Chemical Information

Note: Contains 2 Bottles of Particle Count Suspension (Contains 15 μ m polystyrene spheres in aqueous suspension) and 2 Bottles of Particle Count Blank (aqueous phase without added particles)

Chemical Name(s):	N/A		
2 Bottles of Particle Count Suspension (25 mL each) and 2 Bottles of Particle Count Blank (28 mL each)	CAS Number:	N/A	
	Molecular Formula:	N/A	
	Molecular Weight:	N/A	

Additional Information

The following procedure is recommended to resuspend the particles:

1. Sonicate for 20 seconds
2. Gently invert and/or swirl for 20 seconds
3. Allow to rest up to 2 minutes prior to use



USP REFERENCE STANDARD CERTIFICATE

Label

For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at www.usp.org/sds.	 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 3030 and 4253 counts/mL. Ratio of counts at ≥10 µm to the counts at ≥15 µm: between 1.77 and 2.75. See certificate for any additional information. USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666 Cat. No. 1500502 Material mfd. in United States Lot: R211H0
	 REFERENCE STANDARD PARTICLE COUNT - BLANK 28 mL Contains the aqueous phase without added particles. Do not open until ready to begin test. Store in a refrigerator. PROTECT FROM FREEZING. See certificate for any additional information. USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666 Cat. No. 1500502 Material mfd. in United States Lot: R211H0
<i>Danielle A. Vattimo</i> Quality Assurance	

Certificate Version History

Version Number	Date	Reasons for Change
00 (Current)	02-JUL-2024	First issue



USP REFERENCE STANDARD CERTIFICATE

Label

Reference Standard label typically contains the name, catalog number, lot number, package size, assigned value when applicable, storage conditions, handling instructions, and country of origin information. The label may also include hazard and precautionary statements required by the Occupational Safety and Health Administration (OSHA).

Assigned Value

For USP Reference Standards with compendial quantitative use(s), an assigned value is provided on the label and/or the Certificate.

For USP Reference Standards with compendial qualitative use(s), USP may choose to provide a value, e.g., chromatographic purity, for informational purposes in the Certificate, on a case-by-case basis.

Valid Use Date

It is the responsibility of the user to ascertain that a particular lot of a USP Reference Standard has official status either as a "Current Lot" or as a "Previous Lot" within the assigned valid use date. The online USP Reference Standards Catalog and the online USP Store at www.usp.org are updated daily. USP recommends referring to one of these sources prior to using a USP Reference Standard to make sure the lot is valid for use.

Storage

Storage conditions are lot-specific and may change from one lot to another. Storage conditions on the label and/or the Certificate are valid for unopened container as received. Once the container is opened, unless otherwise specified on the label and/or the Certificate, users are responsible for storing any remaining material according to their site procedures and ensuring continued suitability for its intended use. If no specific directions or limitations are provided on the label, conditions of storage include storage at room temperature and protection from moisture, light, freezing, and excessive heat. See General Chapter <659> in the USP-NF Online for storage and handling definitions.

Instructions for Use

Follow the instructions provided on the label and/or the Certificate and in the associated USP documentary standard(s). Please refer to General Chapter <11> for additional information.

Non-USP Compendial Use

USP Reference Standards are for use in analytical or laboratory applications generally as specified in USP compendia. They are not for use in humans or animals as drugs, food, or medical devices. It may be possible to use a USP RS outside of its associated USP compendial applications; however, it is the responsibility of the user to determine the suitability of the USP RS for a non-USP use.

LEGAL NOTICE

USP WARRANTS GOOD TITLE TO USP REFERENCE STANDARDS ON DISPATCH FROM USP. THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY WARRANTY THAT THE PRODUCTS, INCLUDING THIS CERTIFICATE, ARE OF MERCHANTABLE QUALITY. USP'S LIABILITY ARISING OUT OF OR RELATING TO THE SUPPLY OF USP REFERENCE STANDARDS AND THIS CERTIFICATE SHALL IN NO EVENT INCLUDE LOSS OF PROFITS, COST OF PROCURING SUBSTITUTE GOODS OR SERVICES, OR ANY INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, EVEN IF USP IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, USP DOES NOT WARRANT THAT THE USE OR RESALE OF USP REFERENCE STANDARDS, INCLUDING THEIR USE TO PERFORM TESTS AND ASSAYS PUBLISHED BY USP, WILL NOT INFRINGE UNITED STATES OR ANY OTHER PATENTS.

USP Reference Standards are not intended for use as drugs, food, or as medical devices.

This certificate may not be reproduced without the express written permission of USP.