Designation: D 565 – 99

An American National Standard

Standard Test Method for Carbonizable Substances in White Mineral Oil[1]

This standard is issued under the fixed designation D 565; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope

1.1 This test method covers white mineral oil (Mineral Oil USP and Light Mineral Oil NF) to determine whether it conforms to the standard of quality required for pharmaceutical use as defined by the United States Pharmacopeia and the National Formulary, or the Food and Drug Administration.

1.2 The values stated in SI units are to be regarded as the standard.

1.2.1 The dimensions for the color comparator (see 5.3 and Fig. 1) are excepted for that part of the apparatus.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* For specific hazard statements, see Notes 1-5.

2. Referenced Documents

2.1 *ASTM Standards:*

D 1193 Specification for Reagent Water[2]

D 4057 Practice for Manual Sampling of Petroleum and Petroleum Products[3]

D 4177 Pratice for Automatic Sampling of Petroleum and Petroleum Products[3]

2.2 *Official Compendia:*[4]

United States Pharmacopeia—Current Edition
Monograph on Mineral Oil

National Formulary—Current Edition
Monograph on Light Mineral Oil

2.3 *Government Document:*[5]

21CFR 172.878 Food and Drug Administration Title

3. Summary of Test Method

3.1 The mineral oil is treated with concentrated sulfuric acid (H_2SO_4) under prescribed conditions and the resulting color is compared with a reference standard to determine whether it passes or fails the test.

4. Significance and Use

4.1 This test method is a means for ascertaining whether pharmaceutical mineral oil conforms to the standards of the United States Pharmacopeia, the National Formulary, and the Food and Drug Administration.

5. Apparatus

5.1 *Test Tube*, as shown in Fig. 1, of heat-resistant glass fitted with a well-ground glass stopper, the stopper and the tube bearing identical and indestructible numbers. The tube shall be 140 ± 2 mm in length and between 14.5 and 15.0 mm in outside diameter, and shall be calibrated at the 5 ± 0.2 mL and 10 ± 0.2 mL liquid levels. The capacity of the tube with stopper inserted shall be between 13.6 and 15.6 mL. A rolled edge can be provided for suspending the tube on the cover of the water bath.

5.2 *Water Bath*, suitable for immersing the test tube above the 10 mL line equipped to maintain a temperature of 100 ± 0.5°C. The bath shall be provided with a cover of any suitable material with holes approximately 16 mm in diameter through which the test tubes can be suspended.

5.3 *Color Comparator*, of a suitable type for observing the color of the acid layer in comparison with the reference standard color solution. The size and shape of the comparator are optional, but the size and shape of the apertures shall conform to the dimensions prescribed in Fig. 1.

[1] This test method is under the jurisdiction of ASTM Committee D02 on Petroleum Products and Lubricants and is the direct responsibility of Subcommittee D02.06 on Analysis of Lubricants.

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[2] *Annual Book of ASTM Standards*, Vol 11.01.

[3] *Annual Book of ASTM Standards*, Vol 05.02.

[4] Available from U.S. Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852.

[5] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.