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Microcrystalline Wax

Add the following:

▲$C_{30\leq n\leq 120}H_{2n+2}$with an average carbon chain length number of 50 (C_{50}). Branched-chain hydrocarbons predominate in the mixture. Molecular weight is from about 400 to 1700 with an average molecular weight of 700.

Petroleum wax

CAS RN®: 63231-60-7.▲ (NF 1-Aug-2021)

DEFINITION

Change to read:

Microcrystalline Wax is a ▲refined▲ (NF 1-Aug-2021) mixture of ▲solid saturated aliphatic▲ (NF 1-Aug-2021) hydrocarbons, obtained by solvent fractionation of the still bottom fraction of petroleum by suitable dewaxing or deoiling means.

▲The branched-chain hydrocarbons predominate in the mixture, but the straight-chain and cyclic hydrocarbons are present. It may contain an antioxidant.▲ (NF 1-Aug-2021)

IDENTIFICATION

Add the following:

▲• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197F. Use a thin film of completely melted Microcrystalline Wax when performing 197F.▲ (NF 1-Aug-2021)

Add the following:

▲• **B. Melting Range or Temperature ⟨741⟩, *Procedures, Procedure for Class III*:** 54°–102° and falls within the range indicated by the *Labeling*▲ (NF 1-Aug-2021)

IMPURITIES

Change to read:

• **Residue on Ignition ⟨281⟩**

Sample: 2 g

Analysis: Heat the *Sample* in an open porcelain or platinum dish.▲▲ (NF 1-Aug-2021)

Acceptance criteria: It volatilizes▲▲ (NF 1-Aug-2021) and on ignition yields NMT 0.1%.

SPECIFIC TESTS

• **Color**

Standard solution: Mix 3.8 mL of ferric chloride CS and 1.2 mL of cobaltous chloride CS in a clear-glass, 16- × 150-mm bacteriological test tube.

Sample solution: Melt 10 g of Microcrystalline Wax on a steam bath, and pour 5 mL of the liquid into a clear-glass, 16- × 150-mm bacteriological test tube.

Analysis: Visually compare the contents of both tubes in reflected light against a white background, holding the tubes directly against the background at such an angle that there is no fluorescence.

Acceptance criteria: The *Sample solution* is not darker than the *Standard solution*.

Delete the following:

▲• **Melting Range or Temperature, *Class III* ⟨741⟩:** 54°–102°▲ (NF 1-Aug-2021)

• **Consistency**

Sample: Microcrystalline Wax

Apparatus: Determine the consistency of the *Sample* by means of a penetrometer fitted with a polished metal needle weighing 2.5 ± 0.05 g and having a truncated symmetric tapered angle of 9°0′ ± 15′. The needle is tapered, with a length of 25.4 mm, and the shaft attached to the needle is 58 mm in length and 3.17 mm in diameter. The plunger that fits into the penetrometer and guides the path of the needle weighs 47.5 ± 0.05 g. An additional weight of 50 ± 0.05 g is added to the top of the plunger to give a total load of 100 g.

Analysis: The *Sample* is cast in a brass cylinder open at both ends. The cylinder has an inside diameter of 25.4 mm and is 31.8 mm in height. Place the cylinder on a brass plate wetted with an equal volume mixture of glycerin and water, and place the plate on two corks. Pour the wax, melted at approximately 17° above its congealing point, into the cylinder. Continue pouring the wax until a convex meniscus is formed above the cylinder. Allow the specimen to cool for 1 h at approximately 24°. Shave excess wax from the top of the cylinder, and remove the plate. With the smooth wax surface in the up position, condition the specimen in a water bath at 25° for 1 h.

Arrange the penetrometer so that the wax specimen is completely immersed in the water bath while penetration is run. Lower the needle until the tip just touches the top surface of the specimen. Release the needle for 5 s, and read the depth of penetration in tenths of millimeters. Perform four determinations, and calculate the average value of the four readings.

Acceptance criteria: 3–100 (0.3–10.0 mm)

• **Organic Acids**

Sample solution: 20 g of Microcrystalline Wax in 100 mL of a mixture of neutralized alcohol and water (1:2). Agitate thoroughly, and heat to boiling.

Analysis: To the *Sample solution* add 1 mL of phenolphthalein TS, and titrate rapidly with 0.1 N sodium hydroxide VS, with vigorous agitation, to a sharp pink endpoint in the alcohol–water layer.

Acceptance criteria: NMT 0.4 mL of 0.1 N sodium hydroxide is required.

• **Fixed Oils, Fats, and Rosin**

Sample: 10 g

Sample solution: Digest the *Sample* with 50 mL of sodium hydroxide solution (1 in 5) at 100° for 30 min. Separate the water layer, and acidify it with 2 N sulfuric acid.

Acceptance criteria: No oily or solid matter separates.

• **Alkalinity**

Sample: 35 g

Analysis: Introduce the *Sample* into a 250-mL separator, add 100 mL of boiling water, and shake vigorously for 5 min. Draw off the separated water into a casserole, wash further with two 50-mL portions of boiling water, and add the washings to the casserole. To the pooled washings add 1 drop of phenolphthalein TS, and boil.

Acceptance criteria: The solution does not acquire a pink color.

• **Acidity**

Analysis: If the addition of phenolphthalein TS in the test for *Alkalinity* produces no pink color, add 0.1 mL of methyl orange TS.

Acceptance criteria: No red or pink color is produced.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

Change to read:

• **Labeling:** Label it to indicate the name and proportion of any added ▲antioxidant. Label it to indicate the melting range.▲ (NF 1-Aug-2021)

Add the following:

▲• **USP Reference Standards ⟨11⟩**

USP Microcrystalline Wax RS▲ (NF 1-Aug-2021)

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

Topic/Question	Contact	Expert Committee
MICROCRYSTALLINE WAX	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

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