White, soft paraffin; Yellow soft paraffin (Paraffinum album; Paraffinum flavum)

Chemical name. White and yellow petrolatum.

Other names. White petrolatum, yellow petrolatum; vaselinum album, vaselinum flavum.

Description. A white or a pale yellow to yellow, soft, unctuous mass; odourless.

Solubility. Practically insoluble in water and ethanol (~750 g/l) TS; soluble in ether R, and in most fixed and volatile oils.

Category. Ointment base.

Storage. White and yellow soft paraffins should be kept in a well-closed container.

Additional information. In a thin layer or when melted, both paraffins show a slight fluorescence. Melting point, within 38-60 °C.

Requirements

Definition. White and yellow soft paraffins are purified mixtures of semi-solid hydrocarbons obtained from petroleum. White soft paraffin is bleached. To prevent oil separation, soft paraffins may contain a suitable stabilizer.

Identity tests

A. Melt 2 g until a homogeneous mass is obtained and immediately add 2 mL of water and 0.2 mL of iodine (0.1 mol/l) VS. Heat; as soon as two liquid phases are obtained, shake and cool; the upper solid phase should have a pinkish violet colour.

B. Heat a small quantity of either White soft paraffin or Yellow soft paraffin and ignite; a luminous flame is observed and a deposit of carbon is formed.

Sulfated ash. Not more than 1.0 mg/g.

Alkalinity. To 35 g add 100 mL of boiling water, cover the beaker, and, while stirring, heat to boiling for 5 minutes. Allow the phases to separate, transfer the aqueous layer to a suitable dish, and wash the paraffin with two portions, each of 50 mL, of boiling water which are added to the dish. Add 1 drop of phenolphthalein/ethanol TS and boil; the colour does not change to pink. (Keep this solution for "Acidity".)

Acidity. To the above solution, add 0.1 mL of methyl orange/ethanol TS; the colour does not change to red or pink.

Organic acids. To 20 g add 100 mL of a mixture of equal volumes of neutralized ethanol TS and water, mix thoroughly, and heat to boiling. Add 1 mL of phenolphthalein/ethanol TS and titrate rapidly with carbonate-free sodium hydroxide (0.1 mol/l) VS to a sharp pink end-point, the colour change being observed in the ethanol-water layer; not more than 0.4 mL of carbonate-free sodium hydroxide (0.1 mol/l) VS is required.

Fixed oils, fats, and rosin. Digest 10 g with 50 mL of sodium hydroxide (~200 g/l) TS at 100 °C for 30 minutes. Separate the aqueous layer and acidify with sulfuric acid (~570 g/l) TS; the remaining phase does not show any oil or solid matter.

Ultraviolet absorption. Dissolve 50 mg in 100 mL of 2,2,4-trimethylpentane R. Measure the absorbance of a 1-cm layer at about 290 nm. White soft paraffin does not exceed 0.5; yellow soft paraffin does not exceed 0.75.