



Edition: BP 2025 (Ph. Eur. 11.6 update)

White Soft Paraffin¹



[General Notices](#)

White Petroleum Jelly

(*Ph. Eur. monograph 1799*)

Ph Eur

DEFINITION

Purified and wholly or nearly decolourised semi-solid mixture of hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant.

◇ White soft paraffin described in this monograph is not suitable for oral use. ◇

◆ CHARACTERS

Appearance

White or almost white, translucent, soft unctuous mass, transparent in thin layers even after cooling to 0 °C.

Solubility

Practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol (96 per cent) and in glycerol. ◆

IDENTIFICATION

First identification: A, B, D.

◇ *Second identification:* A, C, D. ◇

A. Drop point: between 35 °C and 70 °C; the value does not differ by more than 5 °C from the value stated on the label. Proceed as described in general method [2.2.17](#) with the following modifications: heat the substance to be examined at 100-105 °C for not more than 10 min, stirring to ensure uniformity. Warm the metal cup at 100-105 °C, remove it from the oven, place on a clean plate or ceramic tile and pour a sufficient quantity of the melted sample into the cup to fill it completely. Allow the filled cup to cool for 30 min on the plate or the ceramic tile at 25 ± 3 °C and place it in a water bath at 24-26 °C for a further 30-40 min. Level the surface of the sample with a single stroke of a knife or razor blade, avoiding compression of the sample. Determine the drop point using a starting temperature of at least 10 °C below the expected drop point and increasing the temperature at a rate of 1 °C/min.

B. Infrared absorption spectrophotometry ([2.2.24](#)).

Preparation Spread a thin film of the substance to be examined.

Comparison [white soft paraffin CRS](#), prepared in the same manner.

- ◇ C. Melt 2 g and when a homogeneous phase is obtained, add 2 mL of [water R](#) and 0.2 mL of [0.05 M iodine](#). Shake. Allow to cool. The solid upper layer is violet-pink or brown. ◇
- D. Appearance (see Tests).

TESTS

Appearance

Melt about 10 g on a water-bath and pour about 5 mL of the resulting liquid into a clear-glass, 15 mm × 150 mm test tube, maintaining the substance in a melted state: it is not more intensely coloured than 5 mL of a mixture of 1 volume of yellow primary solution and 9 volumes of a 10 g/L solution of [hydrochloric acid R](#) in a similar test tube ([2.2.2, Method II](#)). Compare the preparations in reflected light against a white background, holding the tubes directly against the background at such an angle that there is no interfering fluorescence.

Acidity or alkalinity

To 10 g add 20 mL of boiling [water R](#) and shake vigorously for 1 min. Allow to cool and decant. To 10 mL of the aqueous layer add 0.1 mL of [phenolphthalein solution R1](#). The solution is colourless. Not more than 0.5 mL of [0.01 M sodium hydroxide](#) is required to change the colour of the indicator to pink or red.

UV absorbance limit for polycyclic aromatic hydrocarbons

Maximum 75 ppm (expressed as naphthalene equivalent).

Use reagents for ultraviolet absorption spectrophotometry Dissolve 1.0 g in 50 mL of [hexane R](#) which has been previously shaken twice with 10 mL of [dimethyl sulfoxide R](#). Transfer the solution to a 125 mL separating funnel with unlubricated ground-glass parts (stopper, stopcock). Add 20 mL of [dimethyl sulfoxide R](#). Shake vigorously for 1 min and allow to stand until 2 clear layers are formed. Transfer the lower layer to a 2nd separating funnel. Repeat the extraction with a further 20 mL of [dimethyl sulfoxide R](#). Shake the combined lower layers vigorously with 20 mL of [hexane R](#) for 1 min. Allow to stand until 2 clear layers are formed. Separate the lower layer and dilute to 50.0 mL with [dimethyl sulfoxide R](#). Measure the absorbance ([2.2.25](#)) over the range 265 nm to 420 nm using a path length of 1 cm and the clear lower layer obtained by vigorously shaking 10 mL of [dimethyl sulfoxide R](#) with 25 mL of [hexane R](#) for 1 min as compensation liquid. Prepare a reference solution in [dimethyl sulfoxide R](#) containing 6.0 mg of [naphthalene R](#) per litre and measure the absorbance of the solution at the maximum at 278 nm using a path length of 1 cm and [dimethyl sulfoxide R](#) as compensation liquid. At no wavelength in the range 265 nm to 420 nm does the absorbance of the test solution exceed a quarter of that of the reference solution at 278 nm.

[Sulfated ash \(2.4.14\)](#)

Maximum 0.05 per cent, determined on 2.0 g.

◆ STORAGE

Protected from light. ◆

◆ LABELLING

The label states the nominal drop point. ◆

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter [5.15](#)). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is

included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristic may be relevant for white soft paraffin used as a basis in semi-solid preparations.

Consistency

([2.9.9](#), Procedure C): \diamond 60 \diamond to 300. Use the penetrating object described in Figure 2.9.9.-2.

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¹ This monograph has undergone pharmacopoeial harmonisation. See chapter 5.8. *Pharmacopoeial harmonisation*.