## **Quality standards**

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

# **Benzyl Benzoate Application**

#### **General Notices**

Benzyl Benzoate Cutaneous Emulsion

#### **DEFINITION**

Benzyl Benzoate Application is a *cutaneous emulsion*. It contains 25% w/v of Benzyl Benzoate in a suitable oil-in-water emulsified basis.

#### **Extemporaneous preparation**

The following formula and directions apply.

Benzyl Benzoate 250 g

Emulsifying Wax 20 g

Purified Water, freshly boiled and cooled

Sufficient to produce 1000 mL

Melt the <u>Emulsifying Wax</u>, add the Benzyl Benzoate and mix. Pour the mixture into sufficient warm Purified Water to produce 1000 mL and stir thoroughly until cold.

The application complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

#### Content of benzyl benzoate, C<sub>14</sub>H<sub>12</sub>O<sub>2</sub>

23.1 to 26.9% w/v.

#### **ASSAY**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

- (1) Dissolve 1 g of the application in sufficient of the mobile phase to produce 100 mL and dilute 1 volume of the resulting solution to 50 volumes with the mobile phase.
- (2) 0.0050% w/v of benzyl benzoate BPCRS in the mobile phase.

### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (20 cm × 4.6 mm) packed with <u>end-capped octadecylsilyl silica gel for chromatography</u> (10 µm) (Nucleosil C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.5 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 230 nm.
- (f) Inject 20 μL of each solution.

MOBILE PHASE

# https://nhathuocngocanh.com/bp/ 30 volumes of water and 70 volumes of acetonitrile.

DETERMINATION OF CONTENT

Determine the  $\underline{\textit{weight per mL}}$  of the application,  $\underline{\textit{Appendix V G}}$ , and calculate the content of  $C_{14}H_{12}O_2$ , weight in volume, using the declared content of  $C_{14}H_{12}O_2$  in <u>benzyl benzoate BPCRS</u>.