



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

Dichlorophen Tablets

[General Notices](#)

Action and use

Antihelminthic.

DEFINITION

Dichlorophen tablets contain Dichlorophen.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of dichlorophen, $C_{13}H_{10}Cl_2O_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Shake a quantity of the powdered tablets containing 0.1 g of dichlorophen with 50 mL of 0.1M [sodium hydroxide](#) for 15 minutes, add sufficient 0.1M [sodium hydroxide](#) to produce 100 mL, centrifuge and dilute a suitable volume of the supernatant liquid with 0.1M [sodium hydroxide](#) to produce a solution containing 0.002% w/v of dichlorophen. The [light absorption](#) of the resulting solution, [Appendix II B](#), in the range 220 to 350 nm exhibits two maxima, at 245 nm and 304 nm. The [absorbances](#) at the maxima are about 1.3 and about 0.54, respectively.
- B. Shake a quantity of the powdered tablets containing 0.2 g of dichlorophen with a mixture of 5 mL of [water](#) and 5 mL of 5M [sodium hydroxide](#), filter, cool in ice and add a solution prepared by mixing 1 mL of [sodium nitrite solution](#) with a cold solution containing 0.15 mL of [aniline](#) in a mixture of 4 mL of [water](#) and 1 mL of [hydrochloric acid](#). A reddish brown precipitate is produced.
- C. Fuse a quantity of the powdered tablets containing 0.5 g of dichlorophen with 2 g of [anhydrous sodium carbonate](#), cool, extract the residue with [water](#) and filter. The filtrate yields reaction A characteristic [of chlorides](#), [Appendix VI](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions. For solution (1) shake a quantity of the powdered tablets containing 0.50 g of dichlorophen with 20 mL of [methanol](#) for 10 minutes, filter, add 7 mL of [water](#) and dilute to 50 mL with the mobile phase. Solution (2) contains 1.0% w/v of [dichlorophen impurity standard BPCRS](#) in the mobile phase. Solution (3) contains 0.0010% w/v of [4-chlorophenol](#) in the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (20 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (10 µm) (Spherisorb ODS 1 is suitable), (b) as the mobile phase with a flow rate of 1.5 mL per minute a mixture of 1 volume of [glacial acetic acid](#) and 25 volumes of [water](#) and sufficient [methanol](#) to produce a chromatogram with solution (2) closely resembling the reference chromatogram supplied with the impurity standard (75 volumes of [methanol](#) is usually suitable) and (c) a detection wavelength of 280 nm. Record the chromatograms until all of the peaks named on the reference chromatogram have emerged.

In the chromatogram obtained with solution (1) the area of any peak corresponding to 4-chlorophenol is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.1%). Calculate the content of 4,4'-dichloro-2,2'-(2-hydroxy-4-chloro-*m*-xylene- α,α' -diyl)diphenol and the sum of the nominal contents of any other impurities, excluding 4-chlorophenol, with reference to dichlorophen using the declared content of 4,4'-dichloro-2,2'-(2-hydroxy-4-chloro-*m*-

xylene- α,α' -diyl)diphenol in [dichlorophen impurity standard BPCRS](#). The content of 4,4'-dichloro-2,2'-(2-hydroxy-4-chloro-*m*-xylene- α,α' -diyl)diphenol does not exceed 8.0% w/w and the sum of the nominal contents of any other impurities does not exceed 2% w/w.

ASSAY

Weigh and powder 20 tablets. Shake a quantity of the powder containing 0.1 g of dichlorophen with 50 mL of 0.1M [sodium hydroxide](#) for 15 minutes and add sufficient 0.1M [sodium hydroxide](#) to produce 100 mL. Centrifuge, dilute 10 mL of the clear supernatant liquid to 100 mL with 0.1M [sodium hydroxide](#), dilute 20 mL of this solution to 100 mL with 0.1M [sodium hydroxide](#) and measure the [absorbance](#) of the resulting solution at the maximum at 304 nm, [Appendix II B](#). Calculate the content of $C_{13}H_{10}Cl_2O_2$ taking 275 as the value of $A(1\%, 1\text{ cm})$ at the maximum at 304 nm.