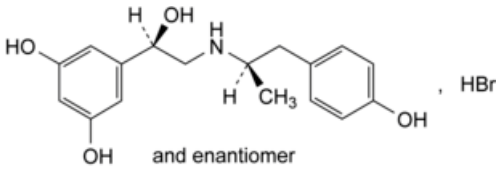
Edition: BP 2025 (Ph. Eur. 11.6 update)

# Fenoterol Hydrobromide

General Notices

*(Ph. Eur. monograph 0901)*




$C_{17}H_{22}BrNO_4$ 384.3 *1944-12-3*

**Action and use**

$Beta_2$-adrenoceptor agonist; bronchodilator.

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## DEFINITION

5-[(1*RS*)-2-[(1*RS*)-2-(4-Hydroxyphenyl)-1-methylethyl]amino-1-hydroxyethyl]benzene-1,3-diol hydrobromide.

**Content**

99.0 per cent to 101.0 per cent (dried substance).

## CHARACTERS

**Appearance**

White or almost white, crystalline powder.

**Solubility**

Soluble in water and in ethanol (96 per cent).

## IDENTIFICATION

A. Infrared absorption spectrophotometry (2.2.24).

*Comparison* *fenoterol hydrobromide CRS*.

B. It gives reaction (a) of bromides (2.3.1).

## TESTS

**Solution S**

Dissolve 2.00 g in *carbon dioxide-free water R* and dilute to 50.0 mL with the same solvent.

**Appearance of solution**

Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution $Y_7$ (*2.2.2, Method II*).

**pH** (*2.2.3*)

4.2 to 5.2 for solution S.

**Related substances**

Liquid chromatography (*2.2.29*). *Prepare the solutions immediately before use*.

*Test solution* Dissolve 6.0 mg of the substance to be examined in *water R* and dilute to 5.0 mL with the same solvent.

*Reference solution (a)* Dilute 1.0 mL of the test solution to 25.0 mL with *water R*.

*Reference solution (b)* Dilute 2.5 mL of reference solution (a) to 100.0 mL with *water R*.

*Reference solution (c)* Dissolve the contents of a vial of *fenoterol for system suitability CRS* (containing impurities A, B and C) in 1 mL of *water R*.

*Column*:

— *size*: *l* = 0.15 m, Ø = 4.6 mm;

— *stationary phase*: *end-capped octadecylsilyl silica gel for chromatography R* (5 µm).

*Mobile phase* Dissolve 24 g of *anhydrous disodium hydrogen phosphate R* in 1000 mL of *water for chromatography R*. Mix 69 volumes of the solution and 1 volume of a 9 g/L solution of *potassium dihydrogen phosphate R*, adjust to pH 8.5 with *phosphoric acid R* and add 35 volumes of *methanol R2*.

*Flow rate* 1.0 mL/min.

*Detection* Spectrophotometer at 215 nm.

*Injection* 20 µL.

*Run time* 3 times the retention time of fenoterol.

*Identification of impurities* Use the chromatogram supplied with *fenoterol for system suitability CRS* and the chromatogram obtained with reference solution (c) to identify the peaks due to impurities A, B and C.

*Relative retention* With reference to fenoterol (retention time = about 7 min): impurity A = about 1.3; impurity B = about 2.0; impurity C = about 2.2.

*System suitability* Reference solution (c):

— *resolution*: minimum 3.0 between the peaks due to fenoterol and impurity A; minimum 1.5 between the peaks due to impurities B and C.

*Limits*:

— *correction factor*: for the calculation of content, multiply the peak area of impurity B by 0.6;

— *impurity A*: not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (4.0 per cent);

— *impurity C*: not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent);

— *impurity B*: not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent);

— *unspecified impurities*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent);

— *sum of impurities other than A*: not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent);

— *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

**Iron** (*2.4.9*)

Maximum 10 ppm.

Dissolve the residue obtained in the test for sulfated ash in 2.5 mL of *dilute hydrochloric acid R* and dilute to 10 mL with *water R*.

**Loss on drying** (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C.

**Sulfated ash** (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

## ASSAY

Dissolve 0.600 g in 50 mL of *water R* and add 5 mL of *dilute nitric acid R*, 25.0 mL of *0.1 M silver nitrate* and 2 mL of *ferric ammonium sulfate solution R2*. Shake and titrate with *0.1 M ammonium thiocyanate* until an orange colour is obtained. Carry out a blank titration.

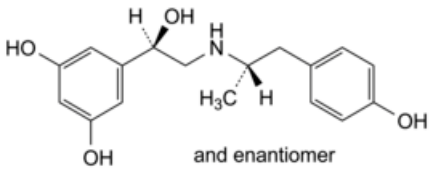
1 mL of *0.1 M silver nitrate* is equivalent to 38.43 mg of $C_{17}H_{22}BrNO_4$.

## STORAGE

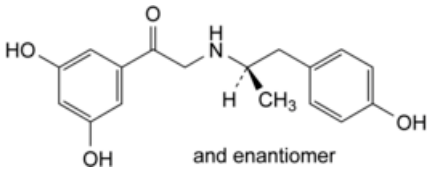
Protected from light.

## IMPURITIES

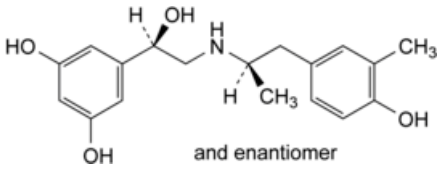
*Specified impurities* *A, B, C.*




A. 5-[(1*RS*)-2-[(1*SR*)-2-(4-hydroxyphenyl)-1-methylethyl]amino-1-hydroxyethyl]benzene-1,3-diol,




B. 1-(3,5-dihydroxyphenyl)-2-[[(1*RS*)-2-(4-hydroxyphenyl)-1-methylethyl]amino]ethan-1-one,




C. 5-[(1*RS*)-2-[(1*RS*)-2-(4-hydroxy-3-methylphenyl)-1-methylethyl]amino-1-hydroxyethyl]benzene-1,3-diol.

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