

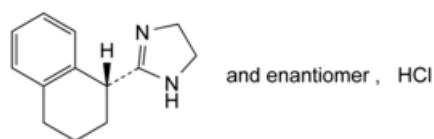


Edition: BP 2025 (Ph. Eur. 11.6 update)

## Tetryzoline Hydrochloride

### [General Notices](#)

(Ph. Eur. monograph 2101)



$C_{13}H_{17}ClN_2$  236.7 522-48-5

### Action and use

Adrenoceptor agonist; decongestant.

Ph Eur

## DEFINITION

2-[(1*RS*)-1,2,3,4-Tetrahydronaphthalen-1-yl]-4,5-dihydro-1*H*-imidazole hydrochloride.

### Content

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

## CHARACTERS

### Appearance

White or almost white, crystalline powder.

### Solubility

Freely soluble in water, in anhydrous ethanol and in ethanol (96 per cent), practically insoluble in acetone.

## IDENTIFICATION

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

Comparison [tetryzoline hydrochloride CRS](#).

B. Dissolve 50 mg in 10 mL of [water R](#). The solution gives reaction (a) of chlorides ([2.3.1](#)).

TESTS

Appearance of solution

The solution is clear (2.2.1) and colourless (2.2.2, Method II).  
Dissolve 1.0 g in water R and dilute to 10 mL with the same solvent.

Related substances

Gas chromatography (2.2.28).  
*Test solution* Dissolve 1.0 g of the substance to be examined in a mixture of 25 volumes of 1 M sodium hydroxide and 75 volumes of methanol R and dilute to 10 mL with the same mixture of solvents.  
*Reference solution* Dilute 1.0 mL of the test solution to 100.0 mL with a mixture of 25 volumes of 1 M sodium hydroxide and 75 volumes of methanol R. Dilute 1.0 mL of this solution to 10.0 mL with a mixture of 25 volumes of 1 M sodium hydroxide and 75 volumes of methanol R.

Column:  
— material: fused silica,  
— size: l = 25 m, Ø = 0.32 mm,  
— stationary phase: methylpolysiloxane R (1 µm).

Carrier gas helium for chromatography R.  
Split ratio 1:40.  
Flow rate 2.5 mL/min.

Temperature:

|                | Time (min) | Temperature (°C) |
|----------------|------------|------------------|
| Column         | 0 - 8      | 160              |
|                | 8 - 11     | 160 → 220        |
|                | 11 - 15    | 220              |
| Injection port |            | 220              |
| Detector       |            | 220              |

Detection Flame ionisation.  
Injection 1 µL.  
Relative retention With reference to tetrazoline (retention time = about 12 min): impurity A = about 0.5.  
System suitability Reference solution:  
— signal-to-noise ratio: minimum 50 for the principal peak.

Limits:  
— impurity A: not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent),  
— any other impurity: for each impurity, not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent),  
— total: not more than twice the area of the principal peak in the chromatogram obtained with the reference solution (0.2 per cent),

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

#### 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.

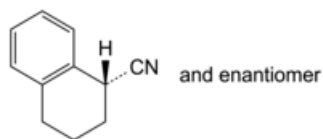
### ASSAY

Dissolve 0.200 g in 100 mL of a mixture of 3 volumes of anhydrous acetic acid R and 7 volumes of acetic anhydride R. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically (2.2.20). Carry out a blank titration.

1 mL of 0.1 M perchloric acid is equivalent to 23.67 mg of  $C_{13}H_{17}ClN_2$ .

### IMPURITIES

*Specified impurities* A.



A. (1RS)-1,2,3,4-tetrahydronaphthalene-1-carbonitrile (α-cyanotetraline).

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