

ERGOTAMINI TARTRAS TRITURATUS

CZ 054:2024

Ergotamine tartrate trituration

DEFINITION

A mixture of ergotamine tartrate ($C_{70}H_{76}N_{10}O_{16}$; *M*. 1313.43) with lactose ($C_{12}H_{22}O_{11}$; *M*. 342.30).

Content. 0.95 % to 1.05 % $C_{70}H_{76}N_{10}O_{16}$ compound.

COMPOSITION AND PROCEDURE

Ergotamini tartras (0224)	1.00 g
Lactosum anhydricum (1061) seu Lactosum monohydricum (0187)	to 100.0 g

In a pre-weighed 150 ml mortar, gradually add anhydrous lactose or lactose monohydrate to the ergotamine tartrate to a total quantity of 100.0 g while stirring thoroughly. Transfer the well-mixed mixture to a wide-mouth dark glass vial with a screw cap.

PROPERTIES

Appearance. A white or almost white crystalline powder.

IDENTIFICATION TESTS

- A.** Dissolve about 0.2 g in 5.0 ml of a *tartaric acid R* solution (10 g/l). The solution fluoresces blue in the light of a mercury lamp with a radiation maximum at 366 nm. The solution is also used for identity test B.
- B.** Add 1.0 ml *water R* and 2.0 ml of *Dimethylaminobenzaldehyde RS6* to two drops of the solution from identity test A; an intense blue colour will appear.
- C.** Mix about 0.1 g with 1.0 ml *silver ammonium nitrate RS* and heat in a water bath; a silver mirror (*tartrate*;) appears.

PURITY TESTS

Loss on drying (2.2.32). At most 1.5% if anhydrous lactose is used; at most 2.5% if lactose monohydrate is used. 0.500 g is dried for 6 hours in a vacuum at 80 °C.

DETERMINATION OF CONTENT

Absorption spectrophotometry in the ultraviolet and visible regions (2.2.25).

The tested solution. Dissolve 0.20 g in a 50 ml graduated flask in a *tartaric acid R* solution (20 g/l) and dilute to 50.0 ml. Add 4.0 ml of this solution to 2.0 ml of *dimethylamino-benzaldehyde RS6*, mix and measure the absorbance (2.2.25) of the resulting solution at 548 nm against the control solution after 30 min.

Reference solution. Dissolve 0.020 g *ergotamine tartrate CRL* in a 50 ml graduated flask in a *tartaric acid R* solution (20 g/l) and dilute to 50.0 ml. Transfer 5.0 ml from this solution to another 50 ml graduated flask and dilute with the same solvent to 50.0 ml. Add 4.0 ml of this solution to 2.0 ml of *Dimethylaminobenzaldehyde RS6*, mix and measure the absorbance (2.2.25) of the resulting solution at 548 nm against the control solution after 30 min.

Control solution. Ke 2.0 ml of a *tartaric acid R* solution (20 g/l), add 4.0 ml *dimethylaminobenzaldehyde RS6*.

Calculate the content of $C_{70}H_{76}N_{10}O_{16}$ as a percentage.

SHELF LIFE

6 months when stored in glass containers at 15 °C to 25 °C and protected from light and moisture.