Evaluation A. The main spot on the chromatogram of the test solution corresponds approximately to the main spot on the chromatogram of reference solution (a).
Detection B. The layer is sprayed with *sulphuric acid* in *ethanol RS* and heated for 10 minutes (or until spots appear) at 120 °C. After cooling, the layer is observed in daylight and ultraviolet light at 366 nm.
Evaluation B. The main spot on the chromatogram of the tested solution corresponds approximately to the position and colour in daylight and to the fluorescence in ultraviolet light at 366 nm and the size of the main spot on the chromatogram of reference solution (a).
Compliance test: There are two distinct spots on the chromatogram of reference solution (b).

B. The refractive index test (see Purity tests) is also an identity test *(propylene glycol).*

PURITY TESTS
Appearance. The tested preparation is clear (2.2.7) and colourless (2.2.2, *Method II).*

Refractive index (2.2.6). 1.431 to 1.433.

DETERMINATION OF CONTENT
Absorption spectrophotometry in the ultraviolet and visible regions (2.2.25).
The tested solution. Dissolve 0.100 g in a 50 ml graduated flask in *Ethanol 96% R* and dilute to 50.0 ml.
Reference solution. Dissolve 0.010 g of *CRL dexamethasone acetate* in a 50 ml flask in *Ethanol 96% R* and dilute to 50.0 ml. Dilute 2.5 ml of this solution with *ethanol 96% R* to 25.0 ml.
Measure the absorbance (2.2.25) of both solutions at the maximum at 238.5 nm.
Evaluation. The absorbance of the tested solution is not greater than that of the reference solution.
The percentage content of C24H31FO6 is calculated using the declared content of *dexamethasone acetate CRL.*

SHELF LIFE
Six months when stored in dark glass containers at 2 °C to 8 °C and protected from light.

ERGOTAMINI TARTRAS TRITURATUS

CZ 054:2024

Ergotamine tartrate trituration

DEFINITION
A mixture of ergotamine tartrate (C70H76N10O16; *Mr* 1313.43) with lactose (C12H22O11; *Mr* 342.30).
Content. 0.95 % to 1.05 % C70H76N10O16 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 *dimethylaminobenzaldehyde RS6* to 2.0 ml of this solution, 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 *dimethylaminobenzaldehyde RS6* to 2.0 ml of this solution, mix and measure the absorbance (2.2.25) of the resulting solution at 548 nm against the control solution after 30 min.

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

Calculate the content of C70H76N10O16 as a percentage.

SHELF LIFE

Six months when stored in glass containers at 2 °C to 8 °C or 15 °C to 25 °C and protected from light and moisture.

ETHACRIDINI LACTATIS SOLUTIO

CZ 055:2023

Ethacridine lactate solution

DEFINITION

A solution of ethacridine lactate (C18H21N3O4.H2O; M_x 361.39).

Content. 90.0 % to 110.0 % of the nominal amount of C18H21N3O4.H2O.