Quality standards

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

Betamethasone Valerate Scalp Application

General Notices

Action and use

Glucocorticoid.

DEFINITION

Betamethasone Valerate Scalp Application is a *cutaneous solution*. It contains Betamethasone Valerate in a suitable liquid basis.

The application complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

Content of betamethasone, C₂₂H₂₉FO₅

90.0 to 115.0% of the stated amount.

IDENTIFICATION

- A. Complies with test A for Identification described under <u>Betamethasone Valerate Lotion</u>, preparing solution (1) by diluting a suitable volume of the application with <u>absolute ethanol</u> to give a solution containing the equivalent of 0.04% w/v of betamethasone.
- B. In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as the peak due to betamethasone valerate in the chromatogram obtained with solution (1).

ASSAY

Carry out the Assay described under <u>Betamethasone Valerate Lotion</u>, preparing solutions (2) and (3) in the following manner. For solution (2) dilute a quantity of the application containing the equivalent of 3 mg of betamethasone to 25 mL with <u>ethanol</u> (65%). For solution (3) add 5 mL of a 0.11% w/v solution of the internal standard to a quantity of the application containing the equivalent of 3 mg of betamethasone and dilute to 25 mL with <u>ethanol</u> (65%).

STORAGE

Betamethasone Valerate Scalp Application should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of betamethasone.

The label indicates the pharmaceutical form as 'cutaneous solution'.

