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Diltiazem Cream

NOTE: This monograph has been developed to cover unlicensed formulations.

Details for the public consultation of this monograph are as follows:

Expert Advisory Group ULM:	**Unlicensed Medicines**
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Deadline for Comment	31st December 2024
Target Publication Date (subject to change)	BP 2026
Notes:	New monograph

Action and use

Calcium channel blocker; used in the treatment of chronic anal fissures.

DEFINITION

Diltiazem Cream contains Diltiazem Hydrochloride in a suitable basis.

The cream complies with the requirements stated under Rectal Preparations and with the following requirements. Where appropriate, the cream also complies with the requirements stated under Unlicensed Medicines.

Content of diltiazem hydrochloride, $C_{22}H_{26}N_2O_4S,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *dichloromethane*.
(1) Mix a quantity of the cream containing 50 mg of Diltiazem Hydrochloride with 25 mL of *dichloromethane*, shake and allow the layers to separate. Centrifuge an aliquot of the lower layer and use the lower layer.
(2) 0.2% w/v of *diltiazem hydrochloride BPCRS* in *dichloromethane*.

(3) Equal volumes of solutions (1) and (2).

CHROMATOGRAPHIC CONDITIONS

(a) Use a *silica gel* F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry it in air and examine immediately under *ultraviolet light (254 nm)*.

MOBILE PHASE

1 volume of 5M *acetic acid*, 6 volumes of *water*, 20 volumes of *dichloromethane* and 24 volumes of *absolute ethanol*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows a single compact spot.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in the mobile phase immediately before use.

(1) Mix a quantity of the cream containing 10 mg of Diltiazem Hydrochloride in 70 mL for 30 minutes, dilute to 100 mL and filter (a 0.45-µm PTFE filter is suitable).
(2) 0.01% w/v of *diltiazem hydrochloride BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (µBondapak C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 240 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

25 volumes of a 0.116% w/v solution of (1*S*)-(+)-*10-camphorsulfonic acid* in 0.1M *sodium acetate*, previously adjusted to pH 6.2 with 0.1M *sodium hydroxide*, 25 volumes of *methanol* and 50 volumes of

acetonitrile.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{26}N_2O_4S,HCl$ in the cream using the declared content of $C_{22}H_{26}N_2O_4S,HCl$ in *diltiazem hydrochloride BPCRS*.

STORAGE

Any special requirements?