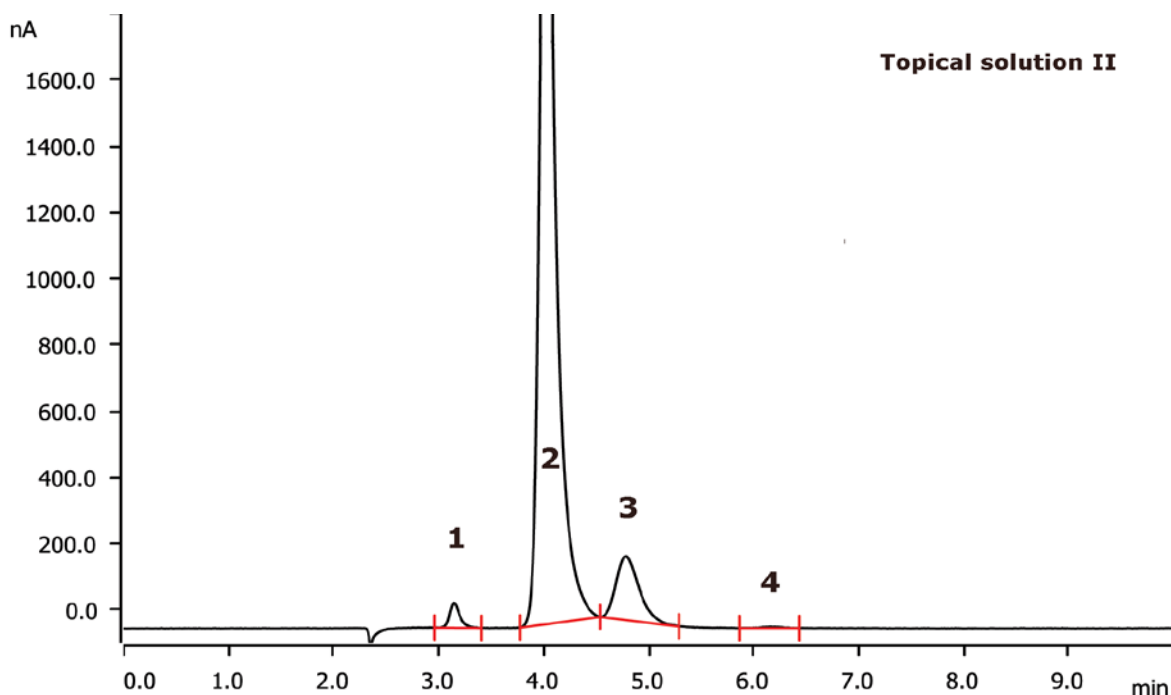


Determination of propylene glycol in diclofenac topical solution



Propylene glycol, also called propane-1,2-diol, is a humectant and applied in topical solutions to increase the solubility of the active pharmaceutical ingredient (API) or the ability to penetrate the skin. In this application, propylene glycol is determined in a placebo and two topical solutions containing diclofenac as the API. The separation is achieved on a Hamilton RCX-30-250/4.0 column with subsequent pulsed amperometric detection (PAD).

Results

3 Propylene glycol	Concentration [mg/g]	Recovery (spiked) [%]
Placebo	< 0.6	-
Topical solution I	101.9	-
Topical solution II	99.8	98

Components 1, 2, and 4 are unknown

Sample

Diclofenac topical solution

Sample preparation

0.1 g of sample is dissolved in 1000 mL of ultrapure water and subsequently injected through 0.2 µm filter.

Columns

Hamilton RCX-30 - 250/4.0	6.1018.000
Metrosep RP 2 Guard/3.5	6.1011.030

Solutions

Eluent	100 mmol/L sodium hydroxide
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Parameters

Flow rate	0.8 mL/min
Injection volume	5 µL
Pmax	34 MPa
Recording time	10 min
Column temperature	ambient

PAD Parameters

Cell	Wall-Jet cell
Working electrode	Gold
Reference electrode	Palladium
Spacer	50 µm
Measuring potential	0.05 V
Measuring duration	100 ms
Cycle duration	550 ms
Measuring range	200 µA
Temperature	35 °C
Mode	PAD

Analysis

Pulsed amperometric detection

Instrumentation

930 Compact IC Flex Oven	2.930.2100
IC Amperometric Detector	2.850.9110
858 Professional Sample Processor	2.858.0020
IC equipment Wall-Jet cell: Carb (Au, Pd)	6.5337.010



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