



APROTININ AND APROTININ CONCENTRATED SOLUTION. DETERMINATION OF IMPURITIES ACCORDING TO *PH. EUR. 0579, 0580*

INTRODUCTION

CAPEL capillary electrophoresis system is a versatile analytical tool for pharmaceutical analysis of proteins, peptides and small molecules using capillary zone electrophoresis (CZE), capillary gel electrophoresis (CGE), capillary isoelectric focusing (CIEF) and micellar electrokinetic chromatography (MEKC). CAPEL capillary electrophoresis system is suitable for the analysis by capillary electrophoresis according to any monograph or general chapter from world pharmacopoeias.

European Pharmacopoeia monographs Aprotinin (0580) and Aprotinin concentrated solution (0579) prescribe the determination of related impurities by capillary zone electrophoresis.

The present method is used for the determination of aprotinin impurities in **aprotinin** and **aprotinin concentrated solution** according to European Pharmacopoeia monographs 0579 and 0580 (Tests section, Des-Ala-aprotinin and des-Ala-des-Gly-aprotinin) using CAPEL capillary electrophoresis system.

MEASUREMENT METHOD

The measurement method is based on capillary zone electrophoresis with direct UV detection at the wavelength of 214 nm.

Sample preparation procedure (dilution) and analysis conditions in accordance with Ph. Eur. 0579, 0580.

EQUIPMENT AND REAGENTS

The CAPEL capillary electrophoresis system is used in measurements. Data acquisition, collection, processing and output are performed using a personal computer running under WINDOWS® XP/7/8/10 operating system with installed dedicated software package ELFORUN.

All reagents according to Ph. Eur. 0579, 0580.

EXAMPLES OF REAL ANALYSES

Ph. Eur. 0579

BGE: according to Ph. Eur. 0579

Capillary: $L_{\text{eff}}/L_{\text{tot}} = 50/60$ cm,
ID= 50 μm

Injection: 105 mbar x sec

Voltage: +12 kV

Temperature: 25 °C

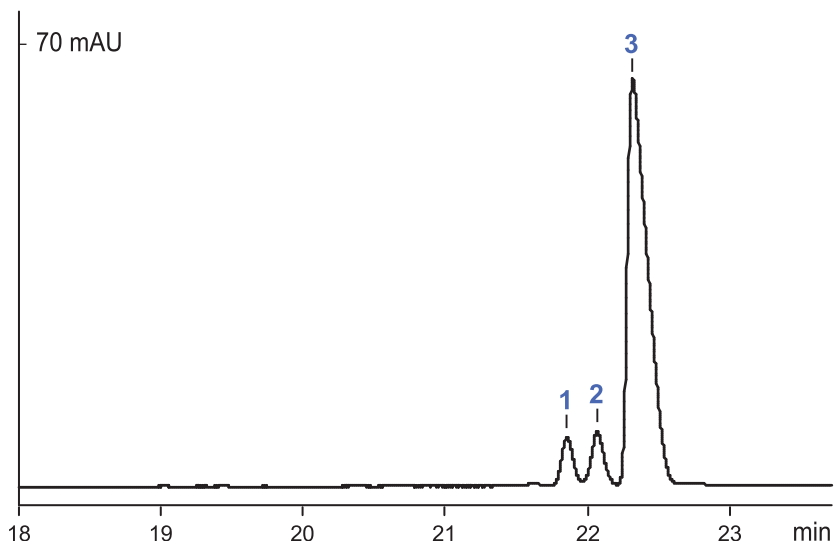
Detection: 214 nm

Sample: Aprotinin preparation

1 – Impurity A

2 – Impurity B

3 – Aprotinin



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To get more specific information, please contact the representative by sales@lumexinstruments.com