



ERYTHROPOIETIN CONCENTRATED SOLUTION. DETERMINATION OF ISOFORMS ACCORDING TO PH. EUR. 1316

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 is suitable for the analysis by capillary electrophoresis according to any monograph or general chapter from world pharmacopoeias.

The present method is used for the determination of erythropoietin (EPO) isoforms in **erythropoietin concentrated solutions** according to European Pharmacopoeia monograph 1316 (Identification, method B. Capillary zone electrophoresis) 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 (desalting, dilution) and analysis conditions in accordance with Ph. Eur. 1316.

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. 1316.

EXAMPLES OF REAL ANALYSES

Ph. Eur. 1316

BGE: according to Ph. Eur. 1316 **Capillary:** $L_{eff}/L_{tot} = 102/112$ cm,

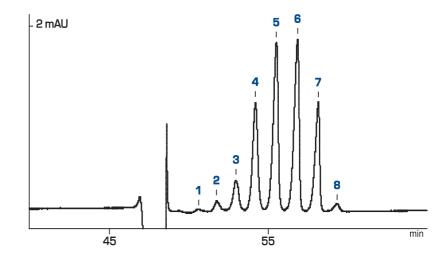
 $ID = 50 \mu m$

Injection: 1000 mbar x sec

Voltage: +16 kV Temperature: 35 °C Detection: 214 nm

Sample: Erythropoietin for physicochemical tests CRS

1-8 - EPO isoforms













CAPEL EXTENDED RANGE OF APPLICATIONS

Besides European Pharmacopoeia method Lumex Instruments specialists demonstrated that CAPEL capillary electrophoresis system can also be applied for express separation of EPO isoforms. This high-speed separation method can be used for screening purposes using the same reagents as for Ph. Eur. 1316. The analysis time as low as 10 minutes can be achieved with just slightly lower resolution.

EXAMPLES OF REAL ANALYSES

High-speed separation method

BGE: according to Ph. Eur. 1316 **Capillary:** $L_{eff}/L_{tot} = 40/50$ cm,

ID= 50 μm

Injection: 300 mbar x sec

Voltage: +25 kV Temperature: 35 °C Detection: 214 nm

Sample: Erythropoietin for physicochemical tests CRS

1-8 - EPO isoforms

