RECOMBINANT THERAPEUTIC MONOCLONAL ANTIBODIES.
DETERMINATION OF PRODUCT-RELATED IMPURITIES ACCORDING TO *USP 129* AND *CH.P 3127*

INTRODUCTION
The present method is used for the determination of product-related impurities in **recombinant therapeutic monoclonal antibodies (Immunoglobulin G, IgG)** according to United States Pharmacopoeia general chapter 129 (Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies, Capillary SDS electrophoresis) using CAPEL-205 capillary electrophoresis system. Alternatively, the determination of IgG impurities in accordance with Chinese Pharmacopoeia general chapter 3127 (Monoclonal antibodies – Determination of molecular size variants (CE-SDS)) can also be performed using CAPEL-205.

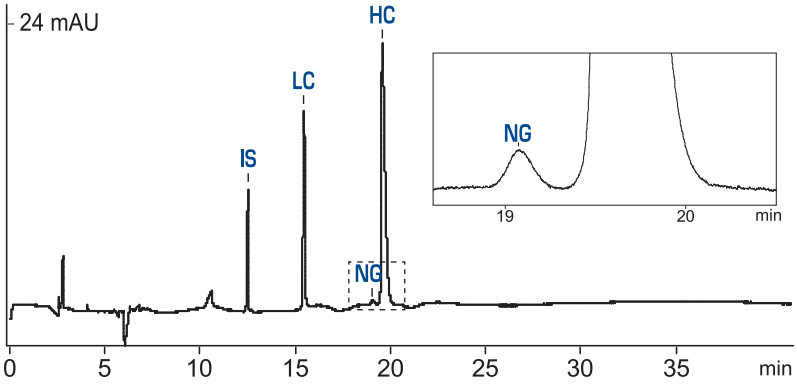
MEASUREMENT METHOD
The measurement method is based on capillary gel electrophoresis (CGE) with direct UV detection at the wavelength of 220 (214) nm. Sample preparation procedure (denaturation with SDS under reducing or non-reducing conditions) and analysis conditions in accordance with USP 129 or Ch.P 3127.

EQUIPMENT AND REAGENTS
The CAPEL-205 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 USP 129 or Ch.P 3127.

EXAMPLES OF REAL ANALYSES

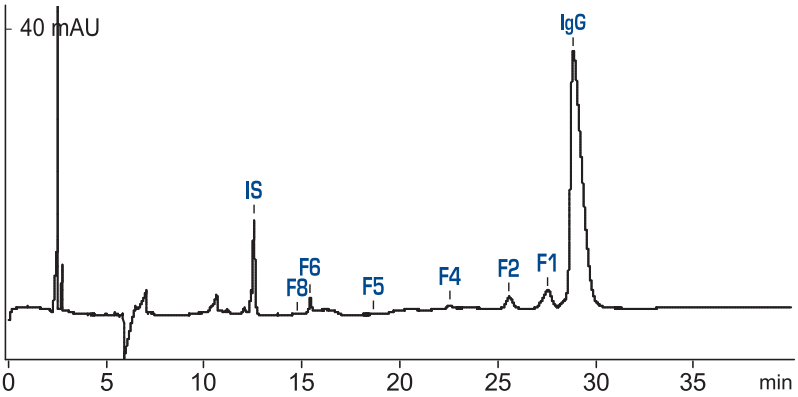
USP 129. Reducing conditions
BGE: gel according to USP 129
Capillary: L_{tot} = 30 cm, ID= 50 µm
Injection: -5 kV x 20 sec
Voltage: -15 kV
Temperature: 25 °C
Detection: 220 nm

Sample: Recombinant IgG preparation
IS – internal standard
LC – light chain
NG – non-glycosylated heavy chain
HC – heavy chain



USP 129. Nonreducing conditions
BGE: gel according to USP 129
Capillary: L_{tot} = 30 cm, ID= 50 µm
Injection: -5 kV x 20 sec
Voltage: -15 kV
Temperature: 25 °C
Detection: 220 nm

Sample: Recombinant IgG preparation
IS – internal standard
F1–F8 – IgG-related impurities (fragments)
IgG – intact antibody



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