INTERLABOR
BELP AG

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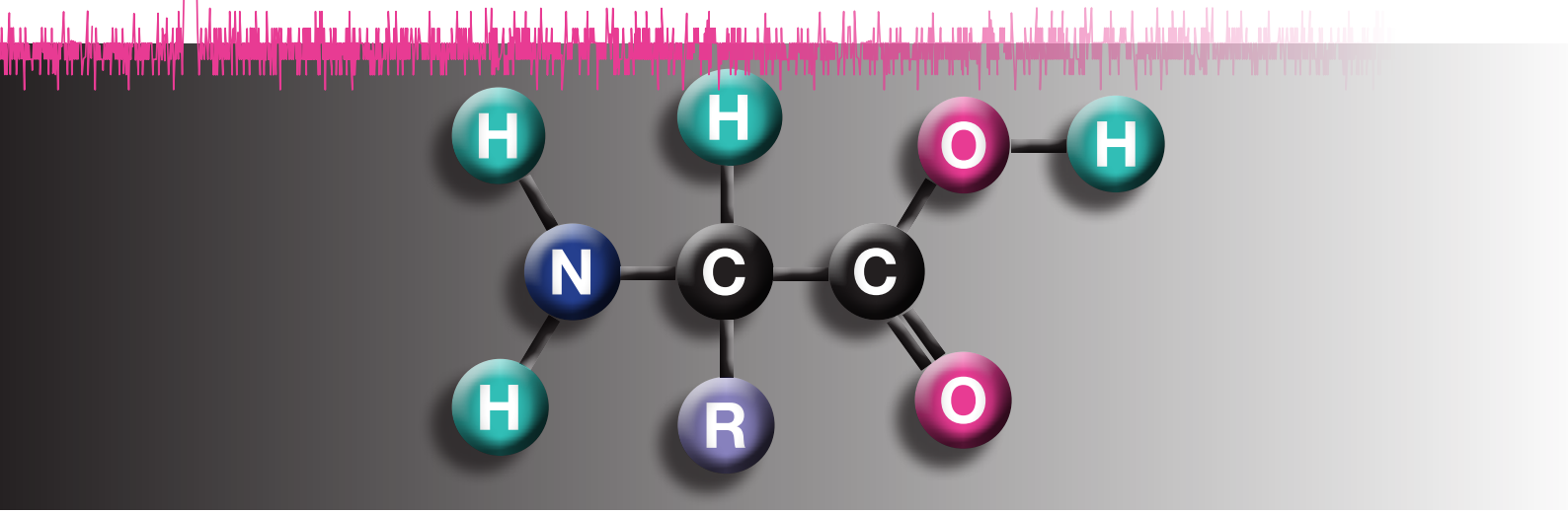
FACTSHEET



Amino acid analysis of pharmaceuticals

Introduction

The importance of biopharmaceuticals in the pharmaceutical market has increased significantly in recent decades. Numerous products such as hormone preparations, coagulation factors or biotechnologically produced vaccines contain active ingredients based on proteins or peptides[1]. Compared to other groups of active ingredients, these are large molecules with a molecular weight of often several thousand Daltons. Since proteins and peptides are extremely sensitive to interfering factors such as light, oxygen, mechanical influences, temperature or pH fluctuations, the production and storage of biopharmaceuticals requires special care. Otherwise, the risk of a change in the structure of the active ingredient, for example, due to denaturation or hydrolysis processes, increases[2].
The qualitative and quantitative determination of amino acids is an important part of the quality control of this type of drugs. Amino acid analysis enables the following aspects of quality assurance to be covered or supported:

- Determination of identity and purity of raw materials for drug production
- Identity and content determination of proteins and peptides in drugs
- Detection of atypical amino acids in drugs (impurities)
- Structure elucidation of existing proteins and peptides

Operating principle amino acid analysis

At INTERLABOR Belp AG, amino acid analysis is based on Chapter 2.2.56 Method I of the European Pharmacopoeia[3]. Basically, the procedure consists of three steps.

First, the free amino acids are separated chromatographically using high-performance liquid chromatography (HPLC) (step 1). Subsequent post-column derivatization with ninhydrin (step 2) enables the final detection of the respective amino acids using an ultraviolet detector (step 3, graph 1).

Key data for amino acid analysis at INTERLABOR Belp AG

Option A:
Raw material analysis according to European Pharmacopoeia
By the described method the raw material analytics can be performed according to the following monographs:

- **Ph.Eur. 01/2017:0752 Alanine**
- **Ph.Eur. 01/2017:0806 Arginine**
- **Ph.Eur. 01/2018:0797 Aspartic acid**
- **Ph.Eur. 01/2017:0782 Phenylalanine**
- **Ph.Eur. 01/2017:0785 Proline**
- **Ph.Eur. 01/2017:0788 Serine**
- **Ph.Eur. 01/2017:1049 Threonine**
- **Ph.Eur. 01/2017:1272 Tryptophan**
- **Ph.Eur. 01/2017:1161 Tyrosine**
- **Ph.Eur. 01/2017:0796 Valine**

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- Minimum quantification disregarding PhEur limit: (Disregarding PhEur limit): 0.05 %.
- Quality of analysis: ISO 17025 or GMP
- Processing time: 10 working days from receipt of sample
- Analysis price: from 1550 CHF per sample

Option B:
Amino acid analysis in pharmaceuticals and food supplements

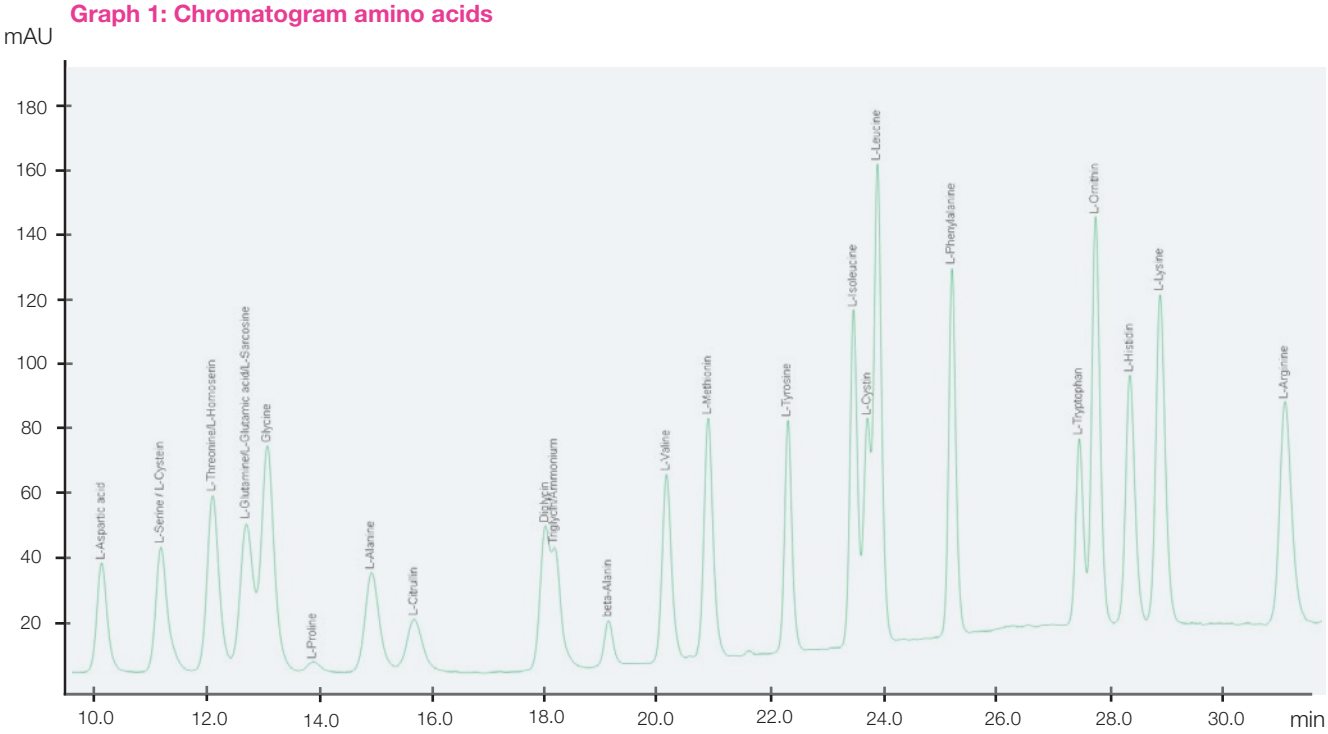
- Development of methods for identity and content determination
- Validation of methods for identity and content determination
- Determination of identity, content and purity in the context of release analysis
- Analytical troubleshooting in case of impurities

Depending on the project, different analysis qualities (state of the art, ISO 17025 or GMP) and processing times (method development and validation about 8-12 weeks) can be offered. We would be happy to advise you in a personal meeting.

References

1. *https://ptaforum.pharmazeutische-zeitung.de/ausgabe-022016/boom-der-biopharmazeutika/*
2. *H.-C. Mahler, J. Thiesen, I. Krämer, Biopharmazeutika Qualitätssicherung bei Transport, Lagerung und Handhabung aus pharmazeutisch-technologischer Sicht, Krankenhauspharmazie 26. Jahrgang Nr. 8 2005*
3. *https://pheur.edqm.eu/app/10-0/content/10-0/20256E.htm?highlight=on&terms=2.2.56*

Graph 1: Chromatogram amino acids



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