Impurities in pure amino acids - Quality Control with post column derivatization and ninhydrin

Introduction

Pure substances are the basis of chemical composition analysis, the accuracy of their purity values determines the level of analysis of related fields in the country. High-purity organic compounds are the material basis for the preparation of standard materials and synthesis of emerging materials: in the stoichiometric value traceability chain, pure materials are at the highest end and are the basis of stoichiometry. The developed countries in the world attach great importance to pure material purity determination technology Research. If the purity of the pure substance or the impurities in it cannot be accurately determined, then the resulting characteristic value of the highest-level national standard material will be biased, thereby transmitting and measuring the value of the chemical composition measurement of the entire country The result was extremely serious.

Amino acid high-accuracy analysis methods and reference materials are widely used in the fields of amino acid production quality control, clinical disease diagnosis, feed quality evaluation, etc., and are of great significance in unifying measurement values and evaluating analysis methods.

According to the European Pharmacopoeia, ninhydrin-positive substances in pure amino acid products are detected by the amino acid analyzer method. Any ninhydrin-positive substance impurities shall not exceed 0.1-0.2%, total impurities shall not exceed 0.5-1.0%, and the reporting limit is 0.05% , Ammonium salt shall not exceed 200ppm (0.02%).

Related method verification content includes:

1. Specificity of EP Pharmacopoeia Method
Confirm applicability of the system to meet the requirements of the Pharmacopoeia, and the peak resolution of isoleucine and leucine is not less than 1.5.
2. Detection limits and quantification limits of related amino acids and ammonia in EP Pharmacopoeia methods Detection limit and quantification limit of arginine, proline and ammonia
3. Linearity of related amino acids and ammonium salts in European Pharmacopoeia
The linearity of arginine, proline and ammonia, for most amino acid derivatives (570nm), the detection limit is 10pmol, and the detection limit of proline and its related derivatives (440nm) is 50pmol. The range is 20pmol to 500pmol, and the linear coefficient of response is above 0.999.
4. Precision Method repeatability: Take a batch of samples to test 6 times, and the RSD of each impurity is ≤5.0%. If it is not reached, it can be appropriately relaxed.
System repeatability: Take a control and repeat the injection 6 times, RSD≤ 5.0%, if not reachable, it can be relaxed appropriately.

Figure 1: Amino Acid Analyzer ARACUS

membraPure ARACUS series automatic Amino Acid Analyzer exclusively adopts the temperature gradient separation technology, which is in accordance with the European Pharmacopoeia Version 9.0 for amino acid analyzers, which can well meet the technical parameters of pharmaceutical companies in the establishment of pharmaceutical analysis methodology. The detection accuracy and repeatability meet all technical requirements in the Europrean Pharmacopoeia and is suitable for testing all kinds of pure amino acids.

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