Detection of sodium in tablet excipients

Introduction:

Pharmaceutical excipients refer to the excipients and additives used in the production of drugs and the formulation. They are important components of pharmaceutical preparations, the material basis for ensuring the production and use of pharmaceutical preparations, and determine the performance, safety, effectiveness and stability of pharmaceutical preparations.Therefore, constantly improving the safety and functional indicators of pharmaceutical excipients and improving the national standard system of pharmaceutical excipients will help promote the quality of pharmaceutical excipients and further ensure the quality of preparations.

Keywords: Excipient, Ion chromatography, sodium.

Instruments and equipment

- **Ion chromatograph**: CIC-D120

Qingdao Shenghan Chromatography Technology Co., Ltd

- **Ultra pure water machine**: UPT-I-20L

Sichuan youpu Chaochun Technology Co., Ltd

- **Electronic balance:** XS204DR

Mettler Toledo (Shanghai) Co., Ltd

Requirements

Reagents

All reagents used are superior grade pure or better,Purchase certified standard solutions Na^+ standard solutions (1000 mg / L).

Deionized Water

When preparing standard samples manually or diluting real samples, please use ASTM filtration and deionization requirements that meet the specifications listed in the table 1.

Table 1: Deionized water specification.

Specification	
Ions Resistivity	≥18.25MΩ·cm
Organics-TOC	<10ppb
Iron/Transition Metals	<1ppb
Pyrogens	<0.03Eu/mL
Particulates（>0.2μm）	<1unit/mL
Colloids-Silica	<10ppb
Bacteria	<1cfu/mL

Sample preparation

Weigh an appropriate amount of sample, dilute it by an appropriate multiple, and pass through 0.22 μ M filter membrane, sample preparation completed.

Table 2:Sample preparation

Sample name	Weight（g）	Absorbent	Constant volume(mL)	Test items
1#	0.0783	Deionized water	100	Na^+

Chromatographic conditions

Eluent: 5 mmol/L MSA（EG）
Flow rate: 1.0 mL/min
Injection volume: 5 μL
Guard column:SH-G-1
Analytical Column: SH-CC-3
Column oven temperature: 35℃
Conductivity cell temperature: 35℃
Suppressor current: 15 mA

Standard chromatogram

Standard chromatogram,As shown in below:

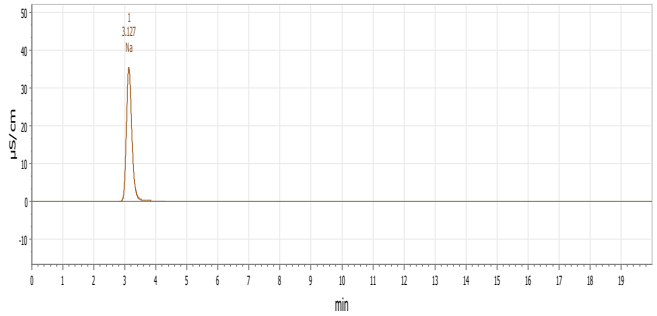

Figure 1. Chromatogram of sodium standard sample.

Table 3:Data of standard solution

Compound name	Retention time[min]	Concentration[mg/L]	Area[(μS/cm)*min]	Height[μS/cm]
Na	3.127	60.00	7.2603	35.4136

Comparison testing (blank)

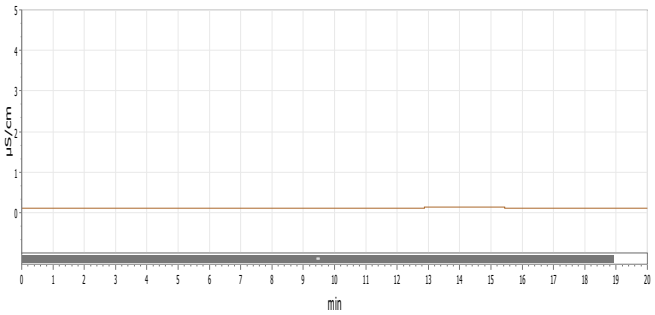

Figure 2.Blank chromatogram

Sample chromatogram

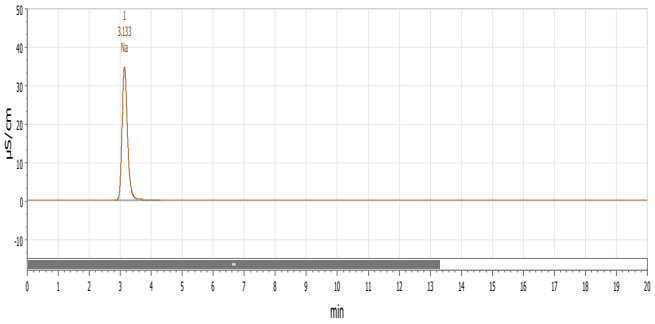

Figure 3. Chromatogram of sample 1#

Results and calculations

Table 4:Sample test results（%）

Sample	Na^+
1#	7.699

Remarks: ① there may be differences in test results between different methods and laboratories; ② It is recommended to use plastic volumetric flask for cation test.

Precautions

It is easy to be polluted in the process of the experiment, and the experimental personnel are required to operate in strict accordance with the operating procedures.

Feasibility analysis and conclusion

Through the above experiments, it is proved that the detection method has good separation and is suitable for the determination of the content of the components to be measured in the sample.