APPLICATION NOTE

Determination of Ammonium in Sodium Bicarbonate using Ion Chromatography.

In pharmacology, Sodium bicarbonate is used for the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Used basically for hemodialysis.

Ammonia is one of the impurities that is present in sodium bicarbonate. Ammonia concentration must be within the specified limit (NMT 20 mg/kg as per USP), as elevated level of ammonia in the blood stream can have adverse effects.

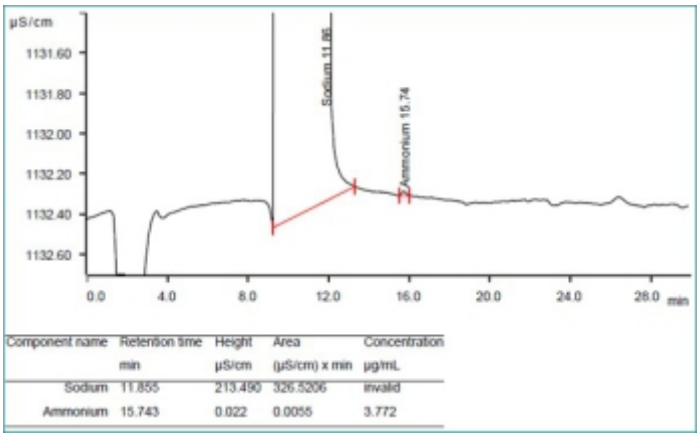
Metrohm

Ion chromatography is a well-accepted technique for the determination of ions in aqueous solution. For most pharmaceutical samples it requires little or no sample preparation or analyte derivatization. Ion chromatography uses an ion-exchange separation followed typically by conductivity, electrochemical, UV absorption, or mass spectrometry detection. Ion chromatography - based procedures are included in several USP monographs and IC has been applied to all aspects of the manufacturing of pharmaceutical products, including the determination of active pharmaceutical ingredients, counter ions, and ionic drug degradation products and ionic process-related impurities.

In sodium bicarbonate USP monograph, ammonia is quantified by Ion chromatography with suppressed conductivity detection method. Here we propose an alternate Ion chromatography method with Non-Suppressed conductivity detection. The proposed method can separate trace level of ammonia in presence of very high concentration of sodium. As it is a non-suppressed method, running & consumable cost are greatly reduced.

Metrohm Ion chromatography (IC) method has been developed keeping in view of all the analytical challenges. The method is very rugged and can be used for precise determinations. The methods were validated with respect to calibration, detection limit and recovery. These methods were successfully applied to pharmaceutical samples.

Sample Chromatogram



Component name	Retention time min	Height µS/cm	Area (µS/cm) x min	Concentration µg/mL
Sodium	11.855	213.490	326.5206	invalid
Ammonium	15.743	0.022	0.0055	3.772

Chromatographic condition

Column	: Metrosep cation exchange column
Mobile Phase	: Nitric acid + 18 - Crown - 6
Flow rate	: 1.2 mL/minute
Column temperature	: 40^{0}C
Detection method	: Non-Suppressed conductivity detection

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