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Ion Chromatographic Method for Quantification of sodium content in Bupivacaine Formulation

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Abstract: A simple, precise, rapid and accurate ion chromatographic method has been developed and validated for the quantification of sodium content in Bupivacaine formulation. Successful quantification of sodium content in Bupivacaine formulation was achieved with in 10min on TSK GEL IC SW cation column 50 x 4.6mm, 5µm column, using a 0.02N Nitric acid and Acetonitrile in the ratio of 100:1v/v at a flow rate of 1.0 mL per minute. The developed ion chromatographic method was validated with respect to specificity, linearity, accuracy, precision, ruggedness and robustness. The method was found to be linear in the range of 1.199 µg.mL^{-}1 to with 7.993 µg.mL^{-}1 with a correlation coefficient of 0.9999. The developed method was validated as per ICH guidelines with respect to specificity, linearity, accuracy, precision and robustness and can be used to evaluate the quality of regular production samples and stability samples.For others provide abstract of maximum 80 words.
Keywords: Bupivacaine; Ion chromatography; Development; Validation

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