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Synthesis of process related impurities of Citicoline and Citicoline sodium[#]

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Citicoline is the diphosphate ester of cytidine. The said compound is sensitive to chemical atmosphere and exhibits formation of process/degradation impurities. Herein is reported a comprehensive synthesis of the pharmacopeia impurities of Citicoline and Citicoline sodium with an objective to provide impurities for better understanding and control in the Citicoline preparation process. This report provides synthetic methodologies for the impurities, considering ease of handling, chemistry and eliminating tedious purification. All the impurities are characterized and the structures confirmed.

Keywords: Citicoline, Citicoline sodium, Cytidine, Cytidine-5'-monophosphate, Impurities