

# Synthesis and Quantification of 2-(Diethylamino)-*N*-(2-methylphenyl)acetamide Nitrate

L. A. Chekryshkina<sup>a</sup>, A. M. Demin<sup>b,\*</sup>, A. A. Tumashov<sup>b,c</sup>, E. A. Babikova<sup>d</sup>, and N. V. Slepova<sup>a</sup>

<sup>a</sup> *Perms State Pharmaceutical Academy, Ministry of Health of the Russian Federation, Perm, Russia*

<sup>b</sup> *Postovskii Institute of Organic Synthesis, Ural Branch, Russian Academy of Sciences, Yekaterinburg, Russia*  
*\*e-mail: demin@ios.uran.ru*

<sup>c</sup> *Institute of Natural Sciences and Mathematics, Ural Federal University, Yekaterinburg, Russia*

<sup>d</sup> *Pharmaceutical Branch, Sverdlovsk Regional Medical College, Yekaterinburg, Russia*

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**Abstract**—A procedure for the synthesis of 2-(diethylamino)-*N*-(2-methylphenyl)acetamide nitrate (*monomecaine*) exhibiting a pronounced antiarrhythmic activity has been optimized. A procedure for its identification and quality control of the drug substance by HPLC has been developed, and the limit of detection of *o*-toluidine impurity therein has been estimated at 0.02%. Procedures for HPLC and extraction–titration quantification of monomecain in the drug substance have been proposed and validated. The obtained relative standard deviation (RSD) indicates good specificity, linearity, and precision of the developed procedures.

**Keywords:** monomecaine, HPLC, extraction titration, validation.

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