Thematic Section: Analytical Research. **Full Paper**
Subsection: Medicinal Chemistry. *Reference Object Identifier* – ROI: jbc-02/15-44-10-149
Publication is available for discussion in the framework of the on-line Internet conference "*Butlerov readings*".
http://butlerov.com/readings/
Contributed: September 15, 2015.

Development and validation of analytical methods for quality control of active pharmaceutical substance Lamivudine

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Keywords*:* lamivudine, validation.

Abstract

Developed analytical methods of quality control of the active pharmaceutical substance Lamivudine on indicators: chromatographic purity and enantiomeric purity. The validation of methods was performed and the suitability of its using for the quality control of APS was confirmed. Appropriate sections of the draft monograph were prepared. On the basis of the validation report appropriate section of the registration dossier was made.