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Catalytic activity of N-terminal methionine modification in recombinant streptokinase expressed in *E. coli*

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Native streptokinase is usually prepared from culture of *Streptococcus equisimilis* for therapeutic purpose of intravenous thrombolytic agent for the treatment of myocardial infarction. The N-terminal amino acid of native streptokinase starts with Isoleucine (I), Alanine (A) and Glycine (G) and followed by Proline (P) etc. The first of amino acid of Isoleucine is playing an important role for the catalytic activity of streptokinase is binding towards inactive plasminogen to activate plasminogen. The specific activity of native streptokinase is 100000 IU/mg with the initial N- terminal isoleucine amino acid. Despite the recombinant streptokinase of N-terminal amino acid begins with methionine and it is a proteinogenic for *E. coli* expression. Comparison for specific activity of recombinant streptokinase shows only 85000IU/mg than 100000IU/mg native streptokinase. The reason behind this objective is that there are two forms (Isomers) of streptokinase are expressed in *E. coli* which was analysed by RP-HPLC and chromogenic assay. We have found that this variation is formed by isomer-1 has 85% of Streptokinase expressed without methionine (85000IU/mg) and Isomer-2 has 15% of streptokinase expressed with methionine (nil activity) in *E. coli*. This phenomenon is clearly demonstrating that the presence and absence of methionine in isomers are varying the streptokinase activity. Hence the methionine alters the streptokinase catalytic activity and is an important role for both activity and immunogenic. This is the first attempt to explore the methionine variation by our method development on RP-HPLC and chromogenic assay for improving the suppression of risk management of myocardial infarction.

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Analytical strategies for the marketing approval in highly regulated markets

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With increasing experience with Biosimilars also the regulator's perspective has further evolved and is based on a fresh scientific principle. The author will provide the latest insights from interactions with regulators worldwide. He will present the current thinking regarding the analytical requirements of both, EMA and FDA. He will highlight the key requirements of today's Biosimilars development and exemplify different strategies to obtain marketing approval.

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