VILNIUS UNIVERSITY
FACULTY OF CHEMISTRY AND GEOSCIENCES

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ANTIBODY HOMOGENEITY METHOD ESTABLISHMENT AND VALIDATION

Master‘s thesis

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(Supeviser science degree, name, surname)

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SUMMARY:

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Antibody Homogeneity Method Establishment and Validation

Immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies are promising therapeutic candidates and several have already been investigated in preclinical studies and clinical trials for therapy of cancer, autoimmune diseases or atherosclerosis. It is increasingly critical to have the ability to accurately assess the amount of aggregates in pharmaceutical products throughout product lifetime, since aggregates cause various toxic side effects.

The aim of this work was optimization of analytical Size Exclusion Chromatography method. Analytical method for IgM and IgG heterogeinity was established and optimized for each imunoglobulin.

For better imunoglobulins lifecycle understanding it was important to evaluate how stress conditions impact aggregation. In order to get this information forced degradation studies for influence of temperature, freeze-thaw, low pH and agitation for antibody heterogeneity were performed.

During lifecycle antibodies may face impurites of other proteins. Thus one of the task of this work, was to evaluate separation efficiency between antibodies and other protein impurities when analysis is performed at optimized conditions of relevant imunoglobulin.

In order to use analytical method for routine analysis, method needs to be validated. One of the tasks of this work was to choose parameters and perform initial qualification experiments of the analytical Size Exclusion Chromatography method for heterogeneity evaluation.