UPPSALA UNIVERSITET

Molecular Biotechnology Programme

Uppsala University School of Engineering

UPTEC X 08 024	**Date of issue 2008-05**

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Title (English)

Implementation of electrochemiluminescence technology for quantification of bioprocess impurities

Title (Swedish)

Abstract

Sensitive analytical techniques are necessary in the biopharmaceutical industry since high demands on purity are required. A new technology from Meso Scale Discovery based on electrochemiluminescence (ECL) has the possibility to replace ELISA, since the ECL assay should be more sensitive and multiple impurities may be analyzed simultaneously. This degree project evaluates the ECL assay and compares the results with ELISA in respect to three impurities, insulin, insulin like growth factor 1 and host cell proteins (HCP) from Chinese hamster ovary (CHO) cells. Insulin and HCP were evaluated both as single analytes and together in a duplex assay in kits from MSD. The insulin singleplex assay correlated well to ELISA and the sensitivity was increased 200 times. For the HCP assay the results correlated well between the single and duplex assay. A comparison of antibodies (Ab's) against CHO HCP using Western blot was also performed. Two Ab preparations are available on the market and it was found that an optimal assay would use a combination of these two.

Keywords

Electrochemiluminescence, ELISA, impurities, host cell proteins, biopharmaceuticals, western blot.

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Project name	Sponsors
Language **English**	Security
ISSN 1401-2138	Classification
Supplementary bibliographical information	Pages **42**

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