

## Abstract

### Employment of HPLC in the field of drug analysis IV.

Diploma thesis

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The diploma thesis is targeted to usage of High Performance Liquid Chromatography in the field of Quality control of drug substances. Methylergometrine is a derivative of ergometrine that belongs to Ergot alkaloids. These native origin substances have strong pharmacological effects on different human body systems already in low concentrations.

Active components from ergot are acquired by extraction and subsequent separation of individual components from a mixture. These substances are repurified. It is very expensive to produce totally pure substances and thus final substances may contain defined amount of impurities.

In case of methylergometrine *Related substances* are analysed according to the valid European pharmacopoeia. Nine substances are in the specification of possible analysed components, tenth component (-)methylergometrinine has not been described in the pharmacopoeia so far.

This thesis deals with development of chromatographic conditions for qualitative separation of a mixture of methylergometrine and its impurities on zirconia based stationary phases. Various stationary phases, e.g. Zr-PBD, Zr-PS, Zr-MS, Zr-CARB, and DiamondBond were tested during the experiments and different mobile phases as well.

A successful separation of all analytes were reached under following conditions, column ZirChrom<sup>®</sup> - PBD, gradient elution, mobile phase – acetonitrile : phosphate buffer (20mmol/l (NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub>, pH = 8,50).

The results are supposed to be used for impurity determination of a methylergometrine substance.