ABSTRACT

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Title of Diploma thesis**:**

HPLC method for separation of chiral impurities of dolutegravir

Following ICH Guidelines Q3A(R2) and Q3B(R2), every new drug substance and every new drug product must be checked for pharmaceutical quality based on Good Manufacturing Practice (GMP).

In this Diploma thesis three batches of a new drug substance and one batch of a new drug product (tablets) are tested by validated analytical method using chiral stationary phase Lux Cellulose-4. This HPLC-UV method is able to separate a main substance which is an antiviral drug - dolutegravir and its stereoisomeric impurities as well as some other related substances.

The main aim is to establish this method as a future monograph method in The International Pharmacopoeia for impurities testing of dolutegravir Sodium.

Impurities in pharmaceutical products have potential carcinogenic, mutagenic, or teratogenic effects. Herein even low chiral contamination of enantiomer and also diastereomer developed through the synthesis of the substance can be detected and separated. Therefore, due to this analytical procedure is possible to insure chiral purity, safety and quality of drug dolutegravir.