

Simple and Accurate HPTLC Method Development and Validation for Gliptin Binary Mixture with Metformin in a Novel Antidiabetic Multicomponent Tablet Dosage Form

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ABSTRACT

Objective: To develop and validate a high-performance thin layer chromatography (HPTLC) for estimation of anti-diabetic medicine comprising of three Gliptin in binary mixture with metformin.

Methods: The chromatographic separation of these drugs was carried out on precoated TLC plates silica gel 60F254 by single mobile phases consisting of Ammonium Sulphate: Methanol: Water (0.2:3:1 v/v) for MET and binary mixture of Saxagliptin (SGP) or vildagliptin (VGP) or either linagliptin (LGP) respectively for ideal separation and good resolution. The densitometric detection and quantification were carried out at 220 nm for MET/LGP and 206 nm for both SGP/MET and VGP/MET. The validation parameters were strictly followed as per the ICH guidelines.

Results: The linearity range was obtained at 0.02-0.2 µg/band for LGP and SGP and 0.2-2 and 2-20 µg/band for VGP and MET, with r^2 value > 0.999. The other parameters such as precision, reproducibility, robustness was efficiently obtained within the limits. The proposed method was successfully applied for simultaneous determination of formulation product.

Conclusion: In simultaneous estimation, the different polarity of drugs makes it more cumbersome to develop and validate any chromatographic method. In the present study, a high-performance thin layer chromatography (HPTLC) for estimation of three drugs Gliptin in Binary mixture with Metformin have been developed and validated to resolve the estimation problem. It is an effortless and speedy method which was developed and validated using ICH guidelines. The developed and validated method using ICH guidelines is effortless and speedy technique.

Keywords: HPTLC, Metformin, Saxagliptin, Vildagliptin, Linagliptin, Validation, Simultaneous, ICH

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