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RESEARCH ARTICLE

Environmentally Friendly Analytical Methods for Quantitative Measurement of Sofosbuvir in Pharmaceutical Formulations: Comparison of HPTLC and UV Spectrophotometric Approaches

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ABSTRACT:

For the quantitative measurement of sofosbuvir (SFR) in pharmaceutical formulation, high-performance thin-layer chromatographic (HPTLC) and environmentally friendly UV spectrophotometric approaches have been developed. HPTLC stationary phases were silica gel 60 F_{254}-coated aluminium plates. Toluene, chloroform, and ethanol were mixed 4:4:1 v/v/v. This mobile phase produced tiny spots of SFR with Rf 0.30±0.01. SFR was densitometrically analysed at 267nm in absorbance mode. Peak area showed great linearity (r2 =0.998) in the dilution range of 100–800ng/spot. A solvent combination of methanol and water was utilised for the UV spectrophotometric technique. First, a stock solution of SFR was made in methanol, and then it was diluted further in water. Absorption maxima were observed at 261nm for the SFR standard solution. Beer-law Lambert's was followed by the SFR at an r2 value of 0.999 at 10-50ng/mL. Both methods met ICH standards for precision, LOD, LOQ, accuracy and specificity. Statistical study validated the methods as reliable and accurate for the estimation of the SFR. The established procedures can be applied to the regular analysis of SFR drugs and pharmaceuticals.

KEYWORDS: Sofosbuvir, HPTLC, UV Spectrophotometry, Method Validation, ICH.

INTRODUCTION:

Sofosbuvir (SFR) is a new nucleotide derivative that has been approved to treat Hepatitis C that has been going on for a long time. The drug's antiviral activities are directed towards the replication protein NS5B in hepatitis C. "A prodrug of the protide class, SFR is transformed to 2'-deoxy-2'-fluoro—C-methyluridine-5'-triphosphate", which terminates viral genome replication. The active form is effective against six of the most common HCV genotypes and stops HCV from reproducing and infecting new cells. Molecular structure of SFR is shown in figure. 1.[1,2].

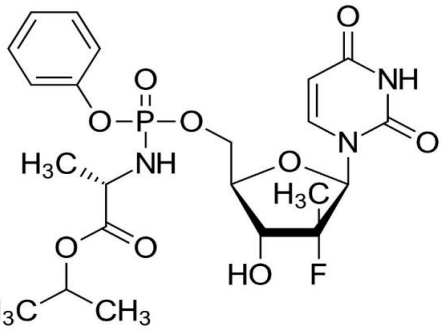

Figure. 1: Chemical structure of SFR

SFR has been shown to be particularly effective against HCV when taken with other medications, both with and without PEGINF. SFR is unique among the directly acting antiviral medications under development due to its high resistance barrier, oral delivery, minimum toxicity, and great efficacy[1,2].

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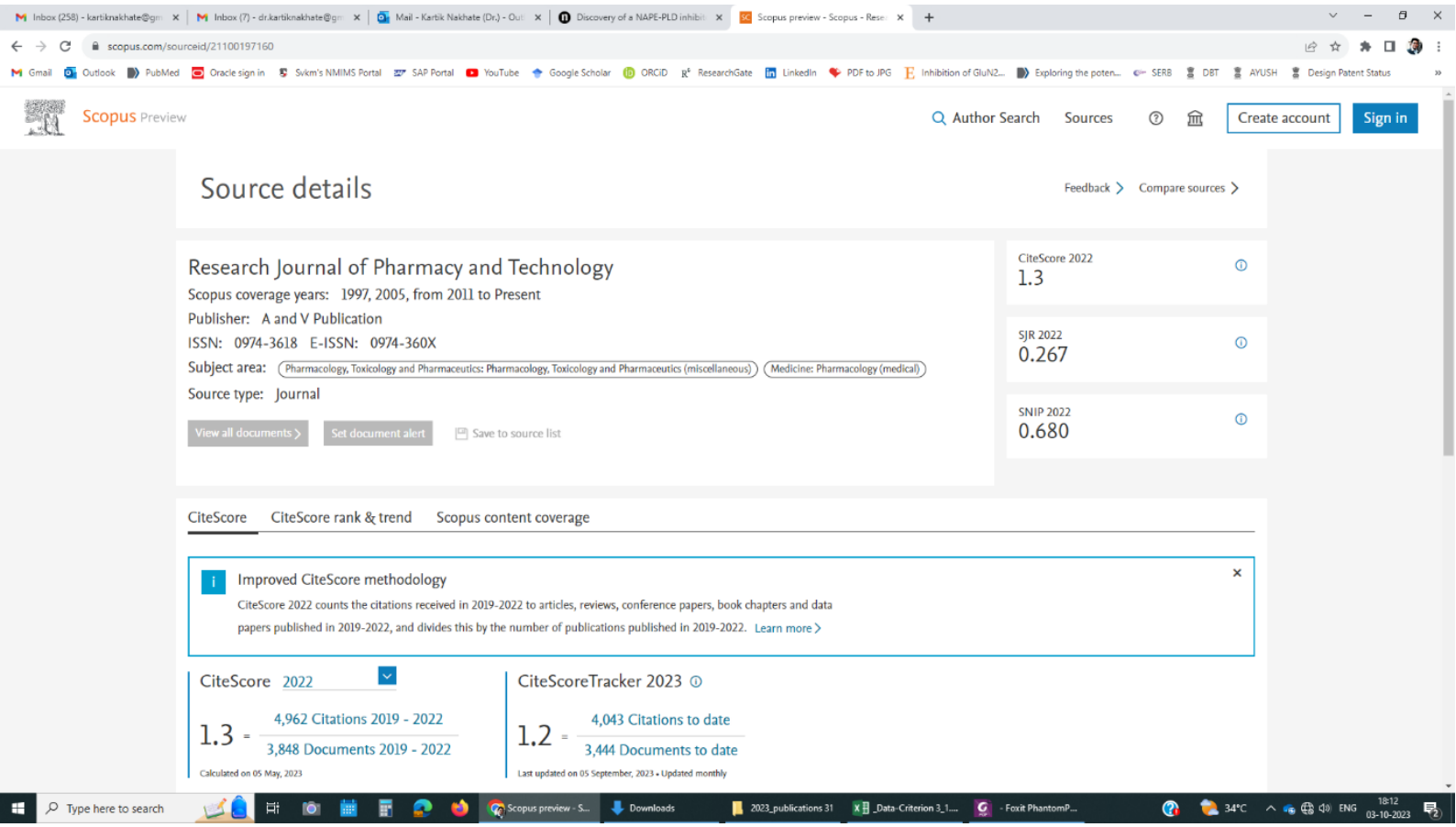
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