DOI: https://doi.org/10.52756/ijerr.2023.v32.034 *Int. J. Exp. Res. Rev.*, Vol. 32: 387-397 (2023)

Original Article | *Peer Reviewed* | *Open Access*

International Journal of Experimental Research and Review (IJERR)

ISSN: 2455-4855 (Online)
www.iaph.in
ISSN 2455-4855

Comparative analysis of analytical method development and its validation for the simultaneous estimation of Bilastine and Montelukast Sodium in bulk and its tablet formulation by planar chromatography

Seema Gosavi[1*], Aditi Kulkarni[2], Sarita Pawar[1], Suchita Dhamane[3], Prasad Gorde[1], Girija Bhavar[4] and Kajal Shirapure[5]

[1]Department of Pharmaceutical Chemistry, Sanjivani College of Pharmaceutical Education and Research, Kopargaon, Affiliated to Savitribai Phule Pune University, Pune, Maharashtra, India; [2]Department of Pharmacognosy, Smt. Kashibai Navale College of Pharmacy, Kondhwa (Bk), Affiliated to Savitribai Phule Pune University, Pune, Maharashtra, India; [3]Department of Pharmaceutics, JSPM's Jayawntrao Sawant College of Pharmacy & Research, Hadapsar, Savitribai Phule Pune University, Pune, Maharashtra, India; [4]Department of Pharmaceutical Chemistry, Shri Vile Parle Kelavani Mandal's Institute of Pharmacy, Dhule, Dr. Babasaheb Ambedkar Technological University, Lonere, Raigad, Maharashtra, India; [5]Department of Quality Assurance Techniques, Sanjivani College of Pharmaceutical Education and Research, Kopargaon, Affiliated to Savitribai Phule Pune University, Pune, Maharashtra, India

E-mail/Orcid Id:

SG, seemagosavi@gmail.com, https://orcid.org/0000-0003-3724-3324; *AK,* aditirjoshi2@gmail.com, https://orcid.org/0000-0003-4200-1987; *SP,* gordesarita@gmail.com, https://orcid.org/0000-0001-5264-157X; *SD,* spd.jscopr@gmail.com, https://orcid.org/0000-0002-5330-170X; *PG,* gordeprasad@gmail.com, https://orcid.org/0000-0001-6356-7918; *GB,* girijabhavar@gmail.com, https://orcid.org/0000-0001-5931-4109; *KS,* shirapurekm2017@gmail.com, https://orcid.org/0009-0002-0874-8251

Article History:
Received: 14th Jun., 2023
Accepted: 22nd Aug., 2023
Published: 30th Aug., 2023

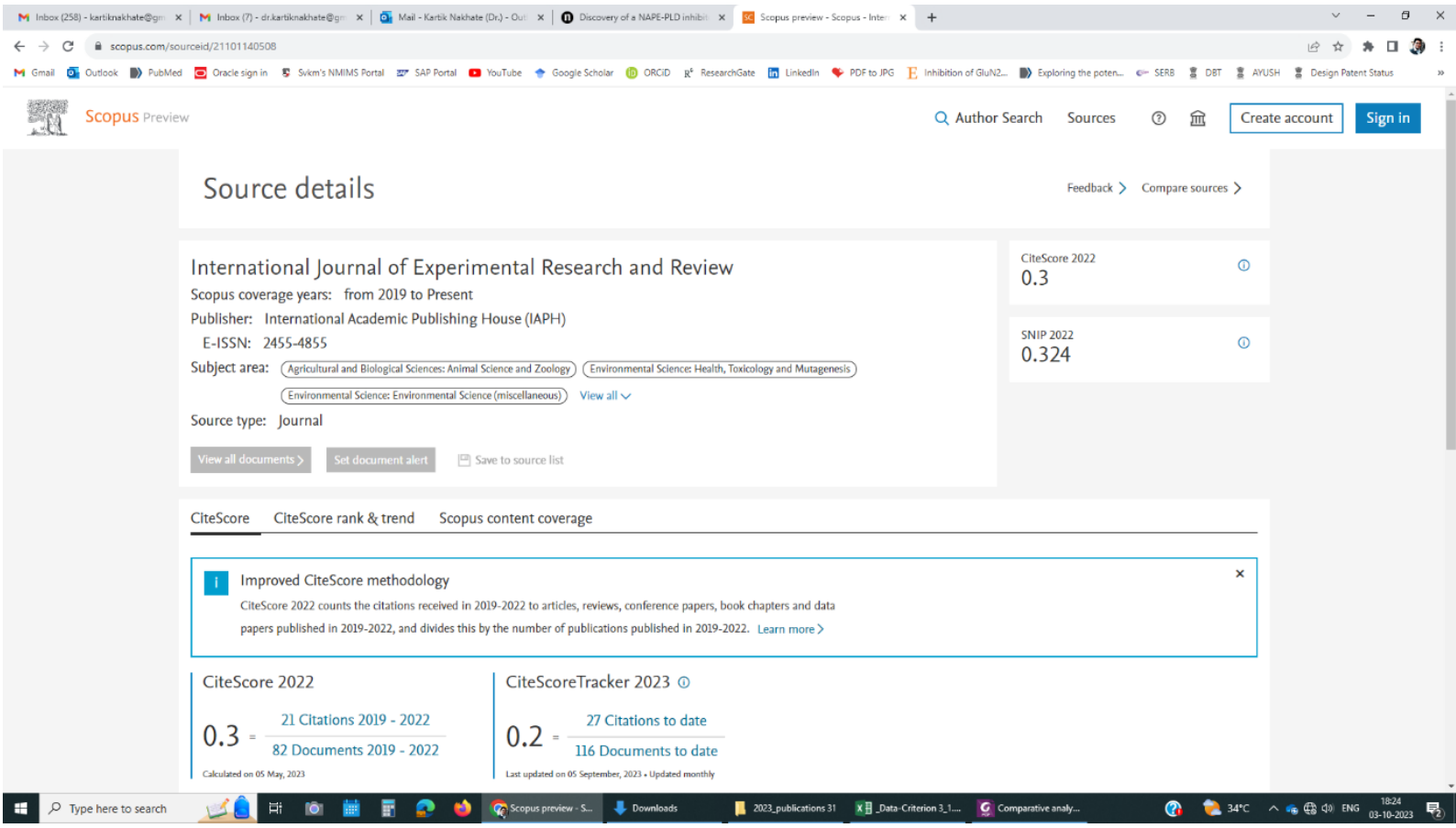
Keywords:
Ertugliflozin, RP-HPLC, Sitagliptin, Tablet

Abstract: The development and validation of analytical methods are crucial in guaranteeing the precision, dependability, and excellence of pharmaceutical analysis. This research investigates the field of pharmaceutical chemistry by doing a comparative examination of analytical techniques for the simultaneous determination of Bilastine and Montelukast Sodium in both bulk and tablet forms. The selected method for this analysis is planar chromatography. The simplicity, specificity, precision, and accuracy of a high-performance liquid chromatography (HPTLC) approach were investigated for their use in the simultaneous estimation of the antihistaminic combination medication Bilastine and Montelukast Sodium in bulk and its pharmaceutical dose for the treatment of allergic rhinitis. Densitometric readings were taken at 254 nm after separating substances using ethyl acetate, toluene, methanol, and ammonia (7:0.5:1.5:0.5v/v/v/v) as mobile phase and precoated aluminium silica gel plates (60F254) as stationary phase. Bilastine and montelukast Sodium have Rf values 0.2 (Bilastine) & 0.4 (Montelukast Sodium), which is considered an acceptable resolution. The International Conference on Harmonization's (ICH) requirements validated the processes for accuracy, linearity, precision, robustness, and system adaptability. Bilastine and Montelukast Sodium concentrations were determined without any disruption from the excipients. Both Bilastine and Montelukast Sodium were effectively quantified using the suggested method, which bodes well for its utility in enhancing quality assurance.

Introduction

Twenty per cent or more of the population in industrialised nations suffers from allergic rhinitis. Independently of or in addition to asthma; allergic rhinitis (AR) has two distinct phases of inflammation, the first of which is marked by sensitization-formation and the development of antigen-specific IgE. In the first stage, mast cells degranulate and release mediators like histamine and tryptase that have already been created or newly synthesised mediators like prostaglandins and

***Corresponding Author:** seemagosavi@gmail.com


Scopus Preview
Author Search
Sources
Create account
Sign in
Source details
Feedback
Compare sources
International Journal of Experimental Research and Review
Scopus coverage years: from 2019 to Present
Publisher: International Academic Publishing House (IAPH)
E-ISSN: 2455-4855
Subject area: Agricultural and Biological Sciences: Animal Science and Zoology
Environmental Science: Health, Toxicology and Mutagenesis
Environmental Science: Environmental Science (miscellaneous)
View all
Source type: Journal
View all documents
Set document alert
Save to source list
CiteScore 2022
0.3
SNIP 2022
0.324
CiteScore
CiteScore rank & trend
Scopus content coverage
Improved CiteScore methodology
CiteScore 2022 counts the citations received in 2019-2022 to articles, reviews, conference papers, book chapters and data papers published in 2019-2022, and divides this by the number of publications published in 2019-2022.
Learn more
CiteScore 2022
0.3 = 21 Citations 2019 - 2022 / 82 Documents 2019 - 2022
Calculated on 05 May, 2023
CiteScoreTracker 2023
0.2 = 27 Citations to date / 116 Documents to date
Last updated on 05 September, 2023 • Updated monthly