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A new validated stability-indicating RP-HPLC method for simultaneous quantification of dolutegravir and lamivudine in bulk and pharmaceutical dosage form

Khaleel Noorbasha^{1*} and Sharmila Nurbhasha²

Abstract

Background: A fresh selective, rapid, accurate, precise and RP-HPLC stability-indicating method was developed and validated for the quantitative simultaneous determination of dolutegravir and lamivudine in the bulk as well as pharmaceutical dosage form. A chromatographic separation was done by using Inertsil ODS 3V (250 × 4.6 mm, 5 μm) column and mobile phase composed of phosphate buffer, pH 3.0:acetonitrile:methanol (50:20:30% w/w/v) with flow rate of 1.0 mL/min, and the detection of eluents was carried out at a wavelength of 257 nm utilizing a PDA detector. The drugs, dolutegravir and lamivudine, were subjected to varied conditions like base hydrolysis, acid hydrolysis, oxidation, thermal, photochemical and UV. The suggested method was analysed statistically and validated to fulfil requirements of International Conference on Harmonisation (ICH) and the validation covered accuracy, precision, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness, ruggedness and specificity.

Results: The retention time of dolutegravir and lamivudine were observed to be 6.36 and 2.16 min, respectively. The method was found to be linear within the range of 14.98 to 91.25 μg/mL for lamivudine and 2.54 to 15.35 μg/mL for dolutegravir. The percentage recoveries (accuracy) for dolutegravir and lamivudine were in the range of 98.35 to 102.14% and 98.01 to 101.5%. The computed relative variance (%RSD) was within the suitable criterion of less than 2.0.

Conclusion: The suggested method was set to be precise as well as stability-indicating since no interfering degradant peaks and excipients were evident. All the peaks of degradation were successfully resolved by the use of the developed analytical method with altered retention times. Results obtained were analysed statistically and found to be acceptable in line with the ICH guidelines. Hence, such method is often employed successfully for routine analysis of active analytes in the bulk as well as pharmaceutical dosage form. It is going to be extended to review for its estimation in plasma and other biological fluids and may even be employed for quality control stability sample estimation and in cleaning method analysis during cleaning validation.

Keywords: Dolutegravir, Lamivudine, RP-HPLC, Acetonitrile, Methanol, Buffer

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Prof. of Drug Substances, Excipients and Related Methodology Abdulrahman Al-Majed,2021-01-16 Profiles of Drug Substances Excipients and Related Methodology Volume 46 contains comprehensive profiles of five drug compounds Darunavir Bisoprolol Betaxolol Rabeprazole and Irbesartan In addition the work contains a chapter reviewing Bioassay Methods and Their Applications in Herbal Drug Research The comprehensive reviews in the book cover all aspects of drug development and the formulation of drugs helping readers understand how the drug development community remains essential to all phases of pharmaceutical development In addition this work answers why such profiles are of immeasurable importance to workers in the field The scope of the Profiles series encompasses review articles and database compilations that fall within one or more of the following five broad categories Physical Profiles of Drug Substances and Excipients Analytical Profiles of Drug Substances and Excipients ADME Profiles of Drug Substances and Excipients Methodology Related to the Characterization of Drug Substances and Excipients and Methods of Chemical Synthesis Contains contributions from leading authorities Presents an excellent overview on the physical chemical and biomedical properties of some regularly prescribed drugs Includes a cumulative index in each volume Profiles of Drug Substances, Excipients, and Related Methodology Harry G. Brittain,2020-03-10 Profiles of Drug Substances Excipients and Related Methodology Volume 45 presents comprehensive reviews of drug substances and additional materials with critical review chapters that summarize information related to the characterization of drug substances and excipients The series encompasses review articles with this release focusing on Azilsartan Medoxomil Piroxicam Carbetapentane Citrate Emtricitabine Etrilotinib Isotretinoin and Meloxicam Contains contributions from leading authorities Informs and updates on all the latest developments in the field of drug substances excipients and methodologies Profiles of Drug Substances, Excipients, and Related Methodology ,2026-05-01 Profiles of Drug Substances Excipients and Related Methodology Volume 51 provides comprehensive profiles of four pharmaceutical compounds Vortioxetine Rosuvastatin Calcium Perindopril and Ferulic Acid In addition it includes a review article concerning Drugs and Polymer Based Local Delivery Systems in the Treatment of Periodontal Diseases Chapters in this new release include Vortioxetine A Comprehensive Profile Rosuvastatin Calcium A Comprehensive Profile Ferulic Acid A Comprehensive Profile Perindopril A Comprehensive Profile Drugs and Polymer Based Local Delivery Systems in the Treatment of Periodontal Diseases Kinetic Exclusion Assay Technology Theory Experimental Aspects and Applications in Concentration Measurements Across Diverse Fields and more No other book series provides this essential information as promptly and pertinently Sections provide review articles and database compilations categorized into five primary domains Physical Profiles of Drug Substances and Excipients Analytical Profiles of Drug Substances and Excipients ADME Profiles of Drug Substances and Excipients Methodology Pertaining to the Characterization of Drug Substances and Excipients and Methods of Chemical Synthesis Provides the synthesis and pathways of physical or biological degradation of selected drug

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Indian Science Abstracts ,2012-03 **Journal of the Chemical Society of Pakistan** Chemical Society of Pakistan,2007 Prajñā ,2014 **Simultaneous Estimation of Some Drugs in Bulk and in their Formulation by Chromatographic Methods.** Satish Gabhe,Kakasaheb Mahadik,Sachin Potawale,Anirudh Thati,2014-04-09 Master s Thesis from the year 2013 in the subject Medicine Pharmacology Pharmacy course MASTER OF PHARMACY Quality Assurance Techniques language English abstract A number of new drug entities modifications of existing ones and multi component formulations are entering the market every year Development of simple analytical methods for analysis of various drugs in multi component formulations is a tricky task for an analytical researcher As analytical techniques are used throughout drug development manufacturing release of drug products the reliability of their results is essential Chromatographic methods are most useful and powerful techniques for qualitative and quantitative determination of drug s Therefore appropriate validation to demonstrate the performance and suitability of the analytical method is much more than a formal requirement Hence there is need to develop and validate correct analytical method for these medicine s This book details Development and validation of HPTLC densitometric method for concurrent estimation of metformin hydrochloride pioglitazone hydrochloride and gliclazide in combined dosage form Development and validation of HPTLC method for simultaneous estimation of moxifloxacin hydrochloride and dexamethasone sodium phosphate in combined pharmaceutical dosage form Development and validation of RP HPLC method for simultaneous estimation of ciprofloxacin hydrochloride and dexamethasone in combined dosage form which is better alternative to existing one The developed analytical methods are simple selective accurate robust and precise with shorter analysis time for the analysis of drug s in combined pharmaceutical dosage forms All the developed HPTLC and HPLC methods have been validated as per ICH Q2 R1 guidelines Developed analytical methods could boost analytical researcher to work more efficiently in the field of analytical method development and validation of Pharmaceutical dosage forms

Development of RP-HPLC Method for Simultaneous Estimation of Two Drugs Rahul Raut,Abdul Fazil,2016-11-04 Simultaneous Estimation of Drugs by Rp-Hplc Mukesh Maithani,2011-01 A new simple rapid selective precise and accurate isocratic RP HPLC assay has been developed for simultaneous estimation of Ciprofloxacin Hydrochloride Ofloxacin Tinidazole and Ornidazole in tablet formulations The separation was achieved by using C 18 column Phenomenax 250 x 4 6mm i d coupled with a guard column of same material in mobile phase Acetonitrile Water Tri ethylamine 25 75 The pH of mobile phase was adjusted to 6 0 0 1 with 50% ortho phosphoric acid The flow rate was 1 0 mL min 1 and the separated drugs were detected using UV detector at the wavelength of 300 nm The retention time of Ciprofloxacin Hydrochloride Ofloxacin Tinidazole and Ornidazole was noted to be 2 7 3 5 4 5 and 5 8 min respectively

indicative of rather shorter analysis time The method was validated as per ICH guidelines The proposed method was found to be accurate reproducible and consistent It was successfully applied for the analysis of these drugs in marketed formulations and could be effectively used for the routine analysis of formulations containing any one of the above drugs or a combination without any alteration in the chromatographic conditions **Anais da Academia Brasileira de Ciências** ,2008

Development And Validation Of Chromatographic Methods For Simultaneous Quantification Of Drugs In Bulk And In Their Formulations: HPLC And HPTLC Techniques Satish Y. Gabhe,Kakasaheb R. Mahadik,Sachin E. Potawale,Anirudh B. Thati,2014-08 This book details 1 Development and validation of a HPTLC densitometric method for concurrent estimation of metformin hydrochloride pioglitazone hydrochloride and gliclazide in combined dosage form 2 Development and validation of a HPTLC method for simultaneous estimation of moxifloxacin hydrochloride and dexamethasone sodium phosphate in combined pharmaceutical dosage form 3 Development and validation of a RP HPLC method for simultaneous estimation of ciprofloxacin hydrochloride and dexamethasone in combined dosage form which is a better alternative to existing ones The developed analytical methods are simple selective accurate robust and precise with shorter analysis time for the analysis of drug s in combined pharmaceutical dosage forms All the developed HPTLC and HPLC methods have been validated as per ICH Q2 R1 guideline Developed analytical methods could boost analytical researchers to work more efficiently in the field of analytical method development and validation of Pharmaceutical dosage forms

Validated Uv Spectrophotometric and Rp-Hplc Method for Two Drugs Ankur Kothari,Sheetal Sharma,2012-08 The proposed method was quite simple and do not require any pretreatment of drugs and tedious extraction procedure The method has wider linear range Hence the data presented in the manuscript Validated UV Spectrophotometric and RP HPLC method development for the simultaneous estimation of Sitagliptin and Simvastatin in marketed Formulation demonstrate that the proposed method is linear and offer advantages of reagent availability and stability less time consumption The statistical analysis proves that the methods are reproducible and selective for the estimation of Sitagliptin and Simvastatin in marketed tablet formulation Thus it can be extended for routine analysis of Sitagliptin and Simvastatin in pharmaceutical industries hospitals and research laboratories These all process is done for the betterment of medicine so that no or less side effects occur **Medicinal & Aromatic Plants Abstracts** ,2008 **Annual Report** University of Poona,2010 **Journal of Scientific & Industrial Research** ,2007 *Oxidized Lipids in Systemic and Lung Inflammatory Models* Kara Renee Schmelzer,2005 **Dairying in a New Global Environment** ,1994 *Analisis* ,1993 *Some Drugs and Herbal Products* IARC Working Group on the Evaluation of Carcinogenic Risks to Humans,International Agency for Research on Cancer,2016 This volume of the IARC Monographs provides an assessment of the carcinogenicity of 14 drugs and herbal products The IARC Monographs Working Group relied mainly on epidemiological studies to evaluate the carcinogenic hazard to humans exposed to the drugs digoxin widely prescribed for the treatment of chronic heart failure pioglitazone used for the

treatment of type 2 diabetes mellitus and hydrochlorothiazide used to treat hypertension Other agents evaluated included the drugs primidone sulfasalazine pentosan polysulfate sodium and triamterene and five herbal products or their components Aloe vera whole leaf extract goldenseal root powder Ginkgo biloba leaf extract kava extract and pulegone In view of the limited agent specific information available from epidemiological studies assessments of these agents relied mainly on carcinogenicity bioassays to reach conclusions as to the carcinogenic hazard to exposed humans

Nutrition Abstracts and Reviews ,2006

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