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Review Article

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF SOLIFENACIN SUCCINATE: REVIEW

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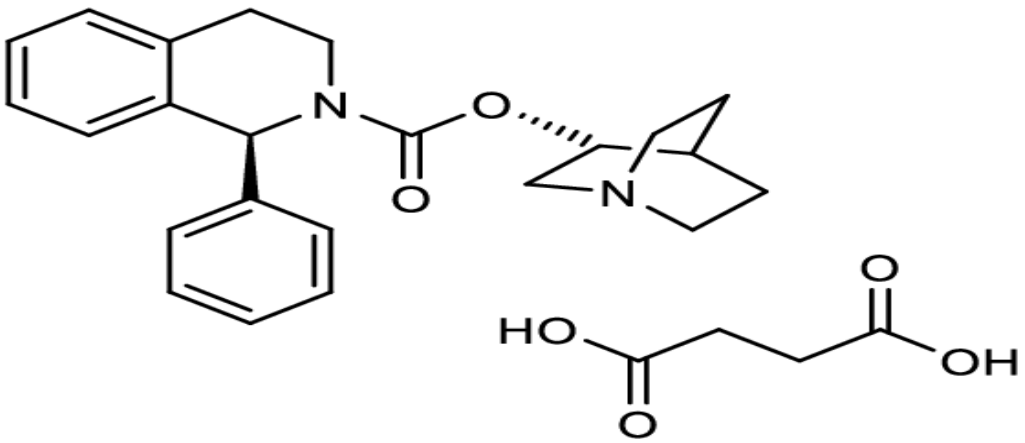
ABSTRACT

Analytical method development and Validation are the continuous and inter-dependent task associated with the research & development, quality control and quality assurance departments. Analytical procedures play a critical role in equivalence and risk assessment, management. It helps in establishment of product-specific acceptance criteria and stability of results. Validations determine that the analytical procedure is suitable for its intended purpose. Literature survey reveals that the analytical methods based on UV spectrometry for the determination of Solifenacin Succinate personally and in combination with different drugs. The parameters were validated according to ICH guideline in terms of accuracy, precision, robustness, and other components of analytical validation. The developed methods are simple, sensitive and reproducible and can be used for the analysis of Solifenacin Succinate in bulk and Tablet dosage form.

KEYWORDS: Solifenacin Succinate, UV, Validation, ICH Guidelines.

INTRODUCTION

Solifenacin is used to treat bladder problems, including neurogenic detrusor over activity and symptoms of an overactive bladder, such as incontinence (loss of bladder control), a strong need to urinate away, or a frequent need to urinate. Solifenacin is a competitive muscarinic receptor antagonist. It has the highest affinity for M3, M1, and M2 muscarinic receptors. 80% of the muscarinic receptors in the bladder are M2, while 20% are M3. Solifenacin antagonism of the M3 receptor prevents contraction of the detrusor muscle, while antagonism of the M2 receptor may prevent contraction of smooth muscle in the bladder.[1]



Solifenacin Succinate is chemically known as (3*R*)-1-azabicyclo[2.2.2]octan-3-yl] (1*S*)-1-phenyl-3,4-dihydro-1*H*-isoquinoline-2-carboxylate;butanedioic acid with a molecular formula of $C_{27}H_{32}N_2O_6$ and a molecular weight of 480.6 g/mol. Solifenacin Succinate drug substance is white crystalline powder and it is Soluble in organic solvent such as ethanol, sulphuric acid, dimethyl sulfoxide, dimethyl Formamide.

REVIEW OF LITERATURE

1. SWATHI NARAPARAJU[2] *et al.,* The present study describes a simple, reliable and reproducible first derivative synchronous spectrofluorimetric method for the simultaneous quantification of tamsulosin hydrochloride and Solifenacin succinate. Tamsulosin hydrochloride was quantified at a wavelength of 322 nm (zero-crossing wavelength point of Solifenacin succinate) and Solifenacin succinate was measured at 570 nm (zero-crossing wavelength point of tamsulosin hydrochloride). Calibration plots were constructed over the concentration range of 2-10 µg/mL for tamsulosin hydrochloride and 30-150 µg/mL for Solifenacin succinate. The method gave satisfactory results when it is validated for linearity, specificity, accuracy, precision, LOD and LOQ as per International Conference on Harmonization (ICH) guidelines. The proposed synchronous analytical method can be employed for routine quality control analysis of tamsulosin hydrochloride/ Solifenacin succinate in tablet dosage forms.

2. G. DIVYA TEJA[3] *et al.,* A Simple, accurate, sensitive, precise and economical spectrophotometric method has been developed for the determination of Solifenacin succinate in tablet formulation. Measurement of ultraviolet absorption at 220 nm. The proposed method was validated statistically. The developed method obeyed Beer's law in the concentration range of 2-10 µg/mL. The limit of detection and limit of Quantitation for estimation of Solifenacin succinate were 0.301786 µg/ml and 0.914505 µg/ml respectively. The recovery was in the range of 99.174 to 101.012 %. The developed method can be used for routine quality control analysis of Solifenacin succinate in pharmaceutical tablet dosage form.

3. M. MADHU KIRAN[4] *et al.,* Two direct, simple visible spectrophotometric methods (Method -I & II) were described for the assay of Solifenacin succinate in pure and in oral dosage forms. The proposed methods (I&II) are based on the ion association complex reactions between the mentioned drug (Solifenacin succinate) and the basic dyes (Methylene blue and Methylene Violet) respectively. Beer-Lambert plots showed good correlation in the concentration range of 2.0-10µg/mL for methods–I & II respectively. The proposed methods were applied to commercially available dosage forms (tablets) of Solifenacin succinate and the results were statistically compared with the results obtained by the reported method7 with recovery studies. The proposed methods offered the advantages of being simple and economical that can be applied without the need for expensive instrumentation and reagents in quality control analysis**.**

4. B. RAKESH[5] *et al.,* To develop a simple and cheap UV spectrophotometric method for the quantitative estimation of Solifenacin succinate (5mg) in tablets and validate as per ICH guidelines. The optimized method uses a solvent 100% triethylammonium phosphate buffer (pH 2.5) for the estimation of assay of Solifenacin succinate in tablets at a detection wavelength of 215 nm. The developed method resulted in Solifenacin succinate exhibiting linearity in the range 5-15µg/ml. The precision is exemplified by relative standard deviation of 1.27%. Percentage Mean recovery was found to be in the range of 98-102, during accuracy studies. The limit of detection (LOD) and limit of quantitation (LOQ) were found to be 1.106µg/ml and 3.35µg/ml respectively. A simple and a cheap UV spectrophotometric method was developed and validated for the quantitative estimation of Solifenacin succinate in tablets as per ICH guidelines and hence it can be used for the routine analysis in various pharmaceutical industries.

5. N.J.R. HEPSEBAH[6] *et al.,* To develop a simple and cheap UV spectrophotometric method for the quantitative estimation of Solifenacin succinate in tablets and validate as per ICH guidelines. The optimized method uses a solvent 0.1 N HCl for the estimation of assay of Solifenacin succinate in tablets at a detection wavelength of 210 nm. System, intraday and inter day precision are exemplified by relative standard deviation of 1.069, 0.58 and 0.77% respectively. The developed method exhibited linearity in the range of 5-15µg/ml. Percentage Mean recovery was found to be in the range of 98-102, during accuracy studies. Accordingly, it is concluded that a simple and a cheap UV spectrophotometric method was developed and validated for the quantitative estimation of Solifenacin succinate in tablets as per ICH guidelines and hence it can be used for the routine analysis in various pharmaceutical industries.

6. ALEXLIVINGSTON M. NADAR[7] *et al.,* The current method development was intended for the determination and quantification of Mirabegron and Solifenacin from a tablet dosage form by using Absorption Ratio Method of UV-Visible Spectroscopic method. Methanol was found to be an appropriate solvent as both the drugs were highly soluble in it, after which the recording of the absorbance was carried out at wavelength maxima (λmax) at 248.8nm and 221.2nm, respectively. Calibration curve was plotted for both the drugs with concentration range of 3-15µg/mL. The plot exhibited a perfect linear relationship for both the drugs with Regression coefficient R^2= 0.9996 and R^2= 0.9999, respectively. The method was found to fulfil all the validation parameters according to ICH guidelines. The method showed good robustness and reproducibility and can be used for the estimation of these drugs from Tablet forms.

7. K. SAI KRUPA RAJ[8] *et al.,* A new simple, accurate and precise first order derivative assay method was developed and validated for the quantitative determination of Solifenacin succinate in bulk and tablets dosage form using UV-visible spectrophotometer. In this method, water was used as solvent, with the absorption maxima of 294 nm. The developed method obeyed

Beer's law in the concentration range of 100-500 µg/ml with correlation coefficient of 0.999. The method showed good reproducibility and precision in this concentration range. The % recovery and % RSD values were found to be within the limits, indicating the method to be accurate and precise, respectively. The LOD and LOQ values were found to be 6.4 µg/ml and 19.4 µg/ml. The validation parameters tested in accordance with the requirements of ICH guidelines, prove the suitability of this method. The proposed method can be used for routine quality control analysis for the estimation of Solifenacin succinate in bulk and tablet dosage form.

8. JENISHA PATEL[9] *et al.,* To develop simple UV derivative spectroscopic and rapid RP-HPLC methods for simultaneous determination of Mirabegron (MB) and Solifenacin succinate (SFS). The chromatographic separation of MB and SFS was performed using Phenomenex Kinetex C18 (150mm × 4.5 mm × 5 µm) analytical column. A mixture of Water: Acetonitrile (20:80%v/v) was considering as mobile phase, at a flow rate of 1ml/min and at detector wavelength 225nm. A linear response was observe over the concentration range 2.5-12.5 µg/ml and 0.5-2.5 µg/ml respectively. The first order derivative method was develop by derivatisation of the zero absorption spectra for the first absorption spectra. The Zero crossing point of MB and SFS at 221 nm and 266 nm was obtain respectively. Beer's law is obey in the concentration range of 7.5-20 µg/ml and 1.5-4 µg/ml for MB and SFS with correlation coefficient (R2) of 0.9984 and 0.9993 respectively. Both the methods were validated in accordance to guidelines for linearity, precision, repeatability, limit of detection (LOD), Limit of Quantification (LOQ), accuracy and robustness. The proposed methods were simple, accurate, precise, and rapid. Therefore, they can be used for regular quality control of MB and SFS formulations and dissolution studies as well.

9. LOKESH SINGH[10] *et al.,* to develop a simple, sensitive, rapid, accurate, and precise spectrophotometric method for the estimation of Solifenacin succinate in tablet dosage forms. For methods I and II, in a series of 10 ml volumetric flasks, aliquots of standard drug solution (100 µg/ml) in double distilled water were transferred and diluted with the same so as to give several dilutions in the concentration ranges of 10 – 60 µg/ml and 10 – 60 µg/ml, respectively, of Solifenacin succinate. To 5 ml of each dilution taken in a separating funnel, (5 ml of bromo thymol blue for method I and 5 ml of bromo phenol blue for method II) and 5 ml of chloroform were added. The reaction mixture was shaken gently for five minutes and allowed to stand so as to separate the aqueous and chloroform layers. The absorbance maxima were measured at 415.6 nm and 412 nm for methods I and II, respectively. The recovery studies were found close to 100%, which indicates the accuracy and precision of the proposed methods. Statistical analysis was carried out, the results of which were found to be satisfactory. Standard deviation values were found to be low and that indicated the reproducibility of the proposed methods.

10. RAKESH BHOOSHANAVIYINA[11] *et al.,* To develop a simple and cheap UV spectrophotometric method for the quantitative estimation of Solifenacin succinate (5mg) in tablets and validate as per ICH guidelines The optimized method uses a solvent 100% triethylammonium phosphate buffer (pH 2.5) for the estimation of assay of Solifenacin succinate in tablets at a detection wavelength of 215. The developed method resulted in Solifenacin succinate exhibiting linearity in the range 5-15µg/ml. The precision is exemplified by relative standard deviation of 1.27%. Percentage Mean recovery was found to be in the range of 98-102, during accuracy studies. The limit of detection (LOD) and limit of quantitation (LOQ) were found to be 1.106µg/ml and 3.35µg/ml respectively A simple and a cheap UV spectrophotometric method was developed and validated for the quantitative estimation of Solifenacin succinate in tablets as per ICH guidelines and hence it can be used for the routine analysis in various pharmaceutical industries.

CONCLUSION

Literature survey suggested that various UV[2-11] and few simultaneous methods were developed and reported. The published methods were validated for various parameters as per ICH guidelines.[12-14] Statistical analysis proved that the published methods were reproducible and selective. Thus, it can be concluded that the reported and published methods can be successfully applied for the estimation of the Solifenacin succinate in pure and pharmaceutical dosage form.

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