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Research article

Development and validation of an eco-friendly UV spectrophotometric method using hydrotropic solubilizing agent for simultaneous estimation of esomeprazole and levosulpiride in solid dosage form

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ABSTRACT

The present study aimed to develop and validate a simple, economical, and eco-friendly UV spectrophotometric method for the simultaneous estimation of Esomeprazole (ESO) and Levosulpiride (LEV) in solid dosage forms using hydrotropic solubilization. Sodium benzoate (2 M) was selected as the hydrotropic agent to enhance the aqueous solubility of both drugs and eliminate the need for hazardous organic solvents. UV spectra were recorded in the range of 200–400 nm. The selected analytical wavelengths were 302 nm for Esomeprazole and 278 nm for Levosulpiride. Simultaneous equation and absorbance ratio methods were employed for quantitative analysis. The developed method was validated according to ICH Q2(R1) guidelines for linearity, accuracy, precision, specificity, robustness, LOD, and LOQ. The method demonstrated good linearity, accuracy, and precision with satisfactory recovery values. The proposed method offers a green analytical alternative for routine quality control analysis of Esomeprazole and Levosulpiride in pharmaceutical formulations.

Keywords: Esomeprazole, Levosulpiride, Hydrotropy, Sodium benzoate, UV spectrophotometry, Green analytical chemistry.

INTRODUCTION

Pharmaceutical analysis is an essential component of drug development and quality assurance. Conventional analytical methods such as HPLC and LC-MS provide high sensitivity and specificity; however, they require expensive instrumentation and large quantities of organic solvents that may pose environmental and health hazards. Therefore, there is increasing interest in developing environmentally friendly analytical methods based on the principles of Green Analytical Chemistry [1].

Hydrotropy is a solubilization technique that enhances the aqueous solubility of poorly water-soluble drugs through the addition of hydrotropic agents such as sodium benzoate, sodium salicylate, and urea. Hydrotropic solubilization minimizes the use of toxic organic solvents and supports sustainable analytical practices [2].

Esomeprazole is a proton pump inhibitor used in the treatment of gastroesophageal reflux disease, peptic ulcer disease, and acid-related disorders. Levosulpiride is a dopamine D2 receptor antagonist with prokinetic activity used in gastrointestinal motility disorders. The combination of these drugs is widely prescribed for the management of GERD and functional dyspepsia. Due to their poor aqueous solubility, analytical estimation of these drugs generally requires organic solvents. Hence, the development of a hydrotropic UV spectrophotometric method is of significant practical importance [3].

MATERIALS AND METHODS

Materials

Esomeprazole (API)

Levosulpiride (API)

Sodium Benzoate (AR Grade)

Distilled Water

Marketed formulation (Esomac-L) [4].

Instrumentation

UV-Visible double-beam spectrophotometer (Shimadzu UV-1800) equipped with matched quartz cells was used for spectral analysis [5].

Selection of hydrotropic agent

Various hydrotropic agents including sodium benzoate, urea, and sodium citrate were evaluated for solubilization efficiency. Sodium benzoate (2 M) exhibited maximum solubility enhancement for both drugs and was selected as the hydrotropic solvent system [6].

Preparation of standard stock solutions

Accurately weighed 10 mg each of Esomeprazole and Levosulpiride were transferred separately into 10 mL volumetric flasks and dissolved in 2 M sodium benzoate solution to obtain stock solutions of 1000 µg/mL [7].

Determination of λmax

The drugs were scanned in the wavelength range of 200–400 nm.

Observed wavelengths:

Esomeprazole: 302 nm

Levosulpiride: 278 nm

Isoabsorptive Point: 284 nm [8].

Method development

Method I: simultaneous equation method

Absorbances were measured at 302 nm and 278 nm, and concentrations were calculated using absorptivity coefficients [9].

Method II: absorbance ratio method (Q-Analysis)

Absorbances were measured at 284 nm and 278 nm, and concentrations were determined using absorbance ratio equations [10].

Method validation

Validation was performed according to ICH Q2(R1) guidelines:

Linearity

Accuracy

Precision

Specificity

Robustness

Limit of Detection (LOD)

Limit of Quantitation (LOQ) [11].

RESULT AND DISCUSSION

Solubility enhancement

Sodium benzoate significantly improved the aqueous solubility of both Esomeprazole and Levosulpiride compared to distilled water, confirming its suitability as a hydrotropic agent [12].

Linearity

The method exhibited excellent linearity over the selected concentration ranges with correlation coefficients greater than 0.999.

Precision

Intra-day and inter-day precision studies showed %RSD values below 2%, indicating good repeatability.

Accuracy

Recovery studies at 80%, 100%, and 120% levels demonstrated satisfactory recoveries within the acceptable range of 98–102%.

Robustness

Minor variations in wavelength and hydrotropic agent concentration did not significantly affect analytical results, indicating robustness [13].

Analysis of marketed formulation

The developed method was successfully applied for the assay of marketed Esomeprazole and Levosulpiride tablets/capsules, and assay values were found within acceptable pharmacopeial limits.

Green analytical assessment

The proposed method eliminates the use of methanol and acetonitrile, thereby reducing environmental impact, analyst exposure, and analytical cost while maintaining analytical performance [14].

CONCLUSION

A simple, accurate, precise, cost-effective, and environmentally friendly UV spectrophotometric method was successfully developed for the simultaneous estimation of Esomeprazole and Levosulpiride using sodium benzoate as a hydrotropic solubilizing agent. The method complies with ICH validation requirements and can be effectively employed for routine quality control analysis of pharmaceutical formulations. The approach supports the principles of Green Analytical Chemistry by eliminating toxic organic solvents and promoting sustainable laboratory practices.

REFERENCES

1. Prabu SL, Shirwaikar A, Shirwaikar A, et al, 2008. Simultaneous estimation of esomeprazole and domperidone by UV spectrophotometric method. Indian J Pharm Sci. 70(1), Pages 128-131. Doi: 10.4103/0250-474X.40351.

2. Pandey MM, Prajapati KB, Vyas AJ, et al, 2020. Development and validation of stability indicating method for simultaneous estimation of esomeprazole and levosulpiride by HPTLC. Asian J Org Med Chem. Doi: 10.14233/AJOMC.2020.AJOMC-P273

3. Chunduri RHB, Dannana GS, 2016. Development and validation of a high-throughput UPLC–MS/MS method for simultaneous quantification of esomeprazole and levosulpiride. J Pharm Anal. 6(3), Pages 190-198. Doi: 10.1016/j.jpha.2016.01.001.

4. Shah DA, 2013. Simultaneous estimation of pantoprazole sodium and levosulpiride in capsule dosage form. ISRN Analytical Chemistry. Doi: 10.1155/2013/459820.

5. Armenta S, Garrigues S, de la Guardia M, 2008. Green analytical chemistry. TrAC Trends Anal Chem. 27(6), Pages 497-511. Doi: 10.1016/j.trac.2008.05.003.

6. Gałuszka A, Migaszewski Z, Namieśnik J, 2013. The 12 principles of green analytical chemistry. TrAC Trends Anal Chem. 50, Pages 78-84.Doi: 10.1016/j.trac.2013.04.010.

7. Tobiszewski M, Mechlińska A, Namieśnik J, 2010. Green analytical chemistry—theory and practice. Chem Soc Rev. Doi: 10.1039/B926439F.

8. Pena-Pereira F, Kloskowski A, Namieśnik J, 2015. Perspectives on green analytical chemistry. Anal Bioanal Chem. Doi: 10.1007/s00216-014-8310-7.

9. Koel M, Kaljurand M, 2006. Application of green chemistry in analytical chemistry. Pure Appl Chem. Doi: 10.1351/pac200678111993.

10. Behera SS, 2021. green analytical chemistry: recent trends and applications. Microchemical Journal. Doi: 10.1016/j.microc.2020.105877.

11. Coffman RE, Kildsig DO, 1996. Hydrotropic solubilization—mechanisms and applications. J Pharm Sci. Doi: 10.1021/js950494m.

12. Poochikian GK, Cradock JC, 1079. Enhanced solubility of drugs by hydrotropy. J Pharm Sci. Doi: 10.1002/jps.2600680623.

13. Maheshwari RK, 2011. Mixed Hydrotropy in Spectrophotometric Analysis. Asian J Pharm Sci. Doi: 10.1016/S1818-0876(11)60020-7.

14. Sonawane S, Gide P, 2011. Application of experimental design for optimization of stability-indicating analytical methods. Arabian Journal of Chemistry. Doi: 10.1016/j.arabjc.2011.02.008.