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Review Article

An Overview of Several Innovative Analytical Techniques Presented on Secnidazole Estimation

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ABSTRACT

Analytical technique development and validation are part of the continuing and interrelated activities associated with research and development, quality assurance, and control. These processes are vital for risk management and equivalence evaluations because they allow the formulation of criteria for product-specific acceptance and generate accurate findings. Analytical methods' appropriateness for their intended uses is verified through validation procedures. A detailed literature analysis reveals that analytical techniques like UV spectroscopy, RP-HPLC, and HPTLC can be used to test Triclabendazole either by itself or in conjunction with other medications. This content appears to be an abstract or summary of a research paper regarding the validation of analytical methods for Triclabendazole. It highlights that the metrics (accuracy, precision, robustness, sensitivity, reproducibility) were evaluated according to ICH guidelines and found suitable for analyzing Triclabendazole in both bulk and tablet forms.

INTRODUCTION

5-nitroimidazoles are the group of antiprotozoal medicines widely used for treatment of infectious diseases caused by Trichomonas, Lamblia, Leishmania, etc. The action mechanism of nitroimidazoles consists in bio chemical reduction of 5-nitrogroup by intracellular transport proteins of anaerobes and protozoa. Reduced nitroimidazoles interact with DNA of microorganism cells and inhibit synthesis of their nucleic acids that leads to microorganism death. Secnidazole is one of the medicines from the group of 5-nitroimidazoles, it is characterized by a prolonged se rum half-life. Chemically, secnidazole is 1-(2 methyl-5-nitroimidazol-1-yl) propan-2-ol. The medicine has a number of side effects manifested by usual symptoms of acute intoxication (nausea, vomiting), especially when interacting with other drugs[1].

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ANALYTICAL METHODS REPORTS ON SECNIDAZOLE

1. **Marcia Regina marcilio *et al*., (2017)**

Secnidazole, a 5-nitroimidazole, is a drug used in the treatment against protozoa, and several bacterial infections. This study purpose was to develop and validate a UV spectrophotometric method to determine secnidazole in pharmaceutical tablet dosage forms once there is no method reported in the pharmacopoeia yet. The quantification was performed using methanol as solvent at 325 nm (maximum wavelength) and three kinds of products marketed in Brazil (reference, generic and similar tablets) containing 1g of Secnidazole. The method obeyed Beer's law in the concentration range of 4 - 20 µgmL-1 respectively. The method was validated according to the International Conference on Harmonization (ICH) and Brazil National Health Surveillance Agency (ANVISA) guidelines, showing accuracy, precision, selectivity, robustness and linearity. Tests such as weight range, friability, disintegration, hardness and dissolution were carried out to check tablets' quality and all the trials showed to be in accordance with the general test guidelines of the Brazilian Pharmacopoeia. The dissolution test was carried out and the developed method was applied. The method developed is suitable for the estimation of secnidazole in tablets without any interference from the excipients and can be used for routine in quality control. Still, it's a simple, fast and low cost method[1].

2. **Jinendra M. Sonpetkar**, ***et al*** **(2012)**

A simple, precise and accurate UV-Spectrophotometric method has been developed and validated for estimation of secnidazole in bulk and tablet dosage form. It shows maximum absorbance at 313 nm with methanol and water (30:70). Estimation was carried out by A(1%1cm) and by comparison with standard. Calibration graph was found to be linear (r2 =0.09998) over concentration range of 1-4µg/ml. The proposed methods appear to be simple, sensitive, and reproducible when checked for parameters like accuracy, precision, limit of detection for routine determination of secnidazole in bulk as well as in tablet. The methods can be adopted in its routine analysis[3].

3. **Mohamed M. Baraka *et al*., (2014)**

Four simple and sensitive spectrophotometric methods were proposed for determination of secnidazole in pure and in tablet forms. The methods (I, II, III) depends on the reduction of secnidazole molecule with zinc dust and hydrochloric acid), forward by coupling reaction between the drug and vanillin reagent in acidic condition (method I), the red colored product was measured at λmax 557 nm. Beer's law was obeyed in the range 5-55 µg/ml. Method II, 1, 2-Naphthoquinone-4 Sulphonate sodium react in alkaline media through nucleophilic substitution reaction producing an orange-brown colored product showing maximum absorption at 480 nm. Beer's law was obeyed in the range 0.2-2.2 µg/ml. Method III, charge transfer complex was formed with tetracyanoethylene with maximum absorbance at 397 nm. Beer's law was obeyed in the range 0.15-1.2 µg/ml. Method IV based on bromination-oxidation reaction using bromate-bromide mixture with methyl orange as reagent and measuring the absorbance of the unbleached dye at 510 nm. Beer's law was obeyed in the range 3-8 µg/ml. Under optimized conditions, the methods were applied successfully to the tablets containing secnidazole. The results obtained are in good agreement with those obtained using official and reference[4].

4. **Oksana V *et al*., (2017)**

Secnidazole is one of the antiprotozoal medicines from the group of 5-nitroimidazoles, which is characterized by a prolonged serum half-life. For secnidazole determination the method of HPLC is widely used, but secnidazole is applied in high concen tration and less sensitive methods of analysis such as spectrophotometry may be useful for its quantification. The aim is to de velop a number of UV-spectrophotometric procedures of secnidazole quantification and carry out step-by-step validation of the developed procedures. UV-spectra of secnidazole in 0.1 M hydrochloric acid solution (A), 96% ethanol (B), 0.1 M potassium hydroxide solution in methanol (C), 0.1 M sodium hydroxide solution (D) have been investigated and it has been set that when in creasing the pH value step-by-step shift of substance maximum absorption to the right is observed (277 nm → 310 nm → 314 nm →319 nm). The procedures of secnidazole quantitative determination by the method of UV-spectrophotometry have been devel oped using the mentioned solvents and wavelengths respectively. Their validation by such parameters as stability, linearity, accu racy and precision in the variants of the method of calibration curve and method of standard has been carried out. The procedures A, B and D of secnidazole quantitative determination are acceptable for application. The best linearity, accuracy and re peatability have been fixed for the procedure D in the variant of the method of calibration curve[5].

5. **Tanzina Sharmin *et al*., (2016)**

Objective of the present work is to develop and validate a simple, cost effective, sensitive and fast HPLC method for the analysis of Secnidazole. A Shimadzu HPLC system with Luna 5µm C18 column is employed for the analysis using Methanol:H2O (60:40, v/v) as mobile phase. Signal from Secnidazole is detected at 310nm by UV Spectrophotometer. The proposed method is fully validated and found to be linear over a workable drug concentration, accurate, precise and robust. This fast and inexpensive method is suitable for research laboratories as well as for quality control analysis in pharmaceutical industries[6].

6. **Ali Gamal Ahmed Al-Kaf1, *et al* (2016)**

A simple, precise, specific, sensitive and accurate stability indicating RP-HPLC method for determination of secnidazole and its degradation products in tablets. The separation was performed on teknokroma, tracer excel C18 column (25cm x 0.46cm.5µm) using mobile phase consisting of water: methanol: acetonitrile in ratio (73: 17: 10). A flow rate was set at 1mL/min; the detection wavelength was set at 228nm. The calibration curves were found to be linear in the concentration range of 50-150/mL (r2 =0.9997) and 0.25-7.5µg/mL (r2 =0.998) at assay level and low-level of secnidazole. The percentage recoveries of secnidazole were 100.76-101.66% and 97.87-102% at assay and low-level, respectively at 95% confidence limit. The intraday precision was 0.553% and 1.35% at assay level and low-level, respectively. The intermediate precision was 0.56% and 3.10% at assay level and low-level, respectively[7].

7. **Xiaoyu Li, *et al* (2006)**

A simple, accurate, precise and sensitive HPLC-UV method was developed for the determination of secnidazole in human plasma. Secnidazole and tinidazole (IS) were extracted from 0.2 mL of human plasma by ethyl acetate. Secnidazole was then separated by HPLC on a Diamond C18 column and quantified by ultraviolet detection at 319 nm. The mobile phase consisted of acetonitrile–aqueous 5 mM sodium acetate (30:70, v/v) containing of 0.1% acetic acid adjusted to pH

4.0, and the flow rate was 1.0 mL/min. The low limit of quantification was 0.1 µg/mL. The method was linear over the concentration range 0.1–25.0 µg/mL (R2 = 1.000). The recovery of secnidazole from human plasma ranged from 76.5 to 89.1%. Inter- and intra-assay precision ranged from 3.3 to 10.7%. Secnidazole in plasma was stable when stored at ambient temperature for 8 h, at −20°C for 2 weeks and at −20°C for three freeze–thaw cycles[8].

8. **O. V. Shovkova, *et al* (**2018)

To develop GLC/FID- and GLC/MS-procedures for the quantitative determination of secnidazole and carry out step-by-step validation of the procedures developed in the variant of the method of additions. Results and discussion. The chromatographic conditions has been chosen for secnidazole determination by the method of GLC in two variants of performance with flame-ionization and mass-spectrometry detection with the temperature program changing during the analysis from 70 °C to 250 °C or 320 °C . Retention times for secnidazole are 8.97 min and 11.74 min. To prove the possibility of application of the procedures proposed in further analysis their validation has been carried out in the variant of the method of additions. Such validation parameters as in-process stability, linearity, accuracy and precision have been estimated by model solutions[9].

9. **Jessica Gonçalvse de Souza Lima *et al* (2018)**

A simple, rapid, economic and green analytical method was validated for the determination of secnidazole in tablets. The aim was to contribute to the green analytical chemistry since it has low use of organic solvent and low production of toxic waste. For the HPLC-UV method, the mobile phase consisted in a mixture of purified water + 0.7 % acetic acid and ethanol (78:22, v/v) at a f low rate of 1.3 mL min-1 on a CN Luna column (250 x 4.6 mm, 5 µm particle size). Ultraviolet detection was performed at 318 nm. The method was linear over the concentration range of 5-100 µg mL-1 (r = 0.9998) with limits of detection andquantitation of 0.533 e 1.615 µg mL-1, respectively. The precision of the method showed RSD less than 2 %. The accuracy determined by the average recoveries was 99.58 %. The secnidazole tablets were subjected to oxidation, acid, alkaline, neutral and photolytic degradation as stress conditions and the method was considered as indicative of stability. The method is adequate and safe to be a great alternative in routine quality control analyzes for determination and quantification of secnidazole tablets[10].

10. **Xiaoyu Li**, ***et al*** (2007)

A simple, accurate, precise and sensitive HPLC-UV method was developed for the determination of secnidazole in human plasma. Secnidazole and tinidazole (IS) were extracted from 0.2 mL of human plasma by ethyl acetate. Secnidazole was then separated by HPLC on a Diamond C18 column and quantified by ultraviolet detection at 319 nm. The mobile phase consisted of acetonitrile–aqueous 5 mM sodium acetate (30:70, v/v) containing of 0.1% acetic acid adjusted to pH 4.0, and the flow rate was 1.0 mL/min. The low limit of quantification was 0.1 µg/mL. The method was linear over the concentration range 0.1–25.0 µg/mL (R2 = 1.000). The recovery of secnidazole from human plasma ranged from 76.5 to 89.1%. Inter- and intra-assay precision ranged from 3.3 to 10.7%. Secnidazole in plasma was stable when stored at ambient temperature for 8 h, at −20°C for 2 weeks and at −20°C for three freeze–thaw cycles. The developed method was successfully applied to the pharmacokinetic and bioequivalence studies between test and reference secnidazole

tablets following a single 500 mg oral dosage to 20 healthy volunteers of both genders. Pharmacokinetics parameters Tmax , Cmax , AUC0−t , AUC0−∞ , T1/2 were determined of both preparations[11].

11. **Monika Bakshi**, ***et al*., (2004)**

The degradation behaviour of secnidazole was investigated under different stress degradation (hydrolytic, oxidative, photolytic and thermal) conditions recommended by International Conferenceon Harmonisation(ICH) using HPLC and LCMS.Astability-indicating HPLC method was developed that could separate drug from degradation products formed under various conditions. Secnidazole was found to degrade significantly in alkaline conditions, oxidative stress, and also in the presence of light. Mild degradation of the drug occurred in acidic and neutral conditions. The drug was stable to dry heat. Resolution of drug and the degradation products formed under different stress studies were successfully achieved on a C-18columnutilizing water–methanol in the ratio of 85:15 and at the detection wavelength of 310nm. The method was validated with respect to linearity, precision (including intermediate precision), accuracy, selectivity and specificity. ©2004 Elsevier B.V. All rights reserved[12].

RESULTS AND DISCUSSION

The reviewed studies demonstrate that secnidazole can be accurately quantified using UV-spectrophotometry, HPLC, and GLC-based methods, each offering distinct advantages. UV methods provided simple, rapid, and cost-effective analysis with good linearity, while derivatization techniques improved sensitivity for low-concentration detection. HPLC methods, particularly stability-indicating procedures, showed superior specificity and precision, effectively separating secnidazole from degradation products and excipients. Bioanalytical HPLC allowed highly sensitive plasma quantification for pharmacokinetic studies. GLC methods also proved reliable with acceptable accuracy and precision. Overall, the findings confirm that multiple validated analytical approaches are suitable for routine quality control, stability assessment, and clinical evaluation of secnidazole.

CONCLUSION

The reviewed spectrophotometric, chromatographic, and stability-indicating studies collectively demonstrate that secnidazole can be accurately and reliably quantified using a variety of analytical techniques. UV-spectrophotometric methods offer simple, rapid, and cost-effective approaches with good linearity and minimal interference, making them suitable for routine quality control of pharmaceutical tablets. Derivatization-based UV procedures further enhance sensitivity when lower detection limits are required. HPLC methods, including stability-indicating and bioanalytical procedures, provide superior specificity, precision, and robustness, enabling effective separation of secnidazole from degradation products and excipients, as well as sensitive detection in biological matrices. GLC methods also present reliable alternatives with acceptable accuracy and precision. Across all studies, validation parameters such as accuracy, precision, linearity, stability, and robustness met international guidelines (ICH/ANVISA). Overall, the findings confirm that multiple validated analytical methods are available for the effective quality assessment, stability evaluation, and clinical monitoring of secnidazole.

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