A review on analytical methods for estimation of Oxaprozin

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Abstract

Oxaprozin is a non-narcotic, non-steroidal, anti-inflammatory drug (NSAID) used to relieve the inflammation, Swelling, stiffness, and joint pain associated with osteoarthritis, and rheumatoid arthritis. Oxaprozin is used to treat rheumatoid arthritis Osteoarthritis, dysmenorrhea and to alleviate moderate pain. This paper explains about the various analytical methods for the estimation of the drug.

Keywords: HPLC; HPTLC; UV; Colarimetry; Voltametry

1. Introduction

Oxaprozin is also known as oxaprozinum is a non-steroidal anti-inflammatory drug. Oxaprozin is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF). The solubility of oxaprozin in ethanol is approximately 15mg/ml and approximately 30mg/ml in DMSO and DMF. Oxaprozin is sparingly soluble in aqueous buffers. Its molecular weight is 293.3g/mol. Its colour is white. Its structure is given in the fig 1.

![Figure 1 Structure of Oxaprozin](image-url)
2. Various analytical methods

2.1. HPLC Methods

Patient aged 26-71 years with stable compensated heart failure and 12 healthy controls matched for age, sex, height, weight, and serum albumin, received a 1200-mg oral dose of the nonsteroidal antiinflammatory agent 4,5-diphenyl-2-oxazolopropionic acid (oxaprozin). Serum oxaprozin levels were measured by high pressure liquid chromatography during the next 14 days. Oxaprozin elimination half-life was not different between controls and CHF patients (63 vs 69 h), but peak serum levels were lower (79 vs 63 micrograms/ml, p less than 0.01), apparent volume of distribution was larger (0.22 vs 0.29 l/kg, p less than 0.05) and clearance tended to be higher, although not significantly so, (0.042 vs 0.053 ml/min/kg) in CHF patients. These differences might have been due to reduced serum protein binding (increased free fraction) in CHF patients (0.25 vs 0.44% unbound, p less than 0.1). After correction for individual values of free fraction, groups did not differ in peak free oxaprozin serum levels (0.20 vs 0.26 micrograms/ml), unbound volume of distribution (92 vs 83 l/kg), or unbound clearance (17.5 vs 15.0 ml/min/kg). Thus protein binding of oxaprozin in the present study was reduced in CHF due either to the underlying disease or to the concurrent medications. This in turn caused reciprocal reduction in total (free plus bound) oxaprozin levels and elevated estimates of volume of distribution and clearance. Although protein binding is altered, CHF causes no significant alteration in distribution of free oxaprozin nor free clearance of oxaprozin, which is accomplished by a combination of oxidation and conjugation.2

A series of 42 healthy male and female volunteers aged 21 to 89 years received a single 1200 mg oral dose of oxaprozin. Kinetics were determined from multiple plasma oxaprozin concentrations measured by H.P.L.C. during 14 days after the dose. Peak plasma oxaprozin concentrations were reached between 3 and 6 h after dosage the majority of subjects, probably reflecting slow absorption from the gastrointestinal tract. Elimination also was slow with a mean half-life of 59 h (range 36 to 92 h). Owing in part to extensive protein binding (mean free fraction 0.0023%), oxaprozin distribution was limited, with apparent volume of distribution averaging 0.25 l/kg. Apparent volume of distribution declined with increasing age, probably reflecting the reduction in lean mass relative to total weight that occurs in the elderly. Total apparent oxaprozin clearance declined with age in men (r = -0.58, P less than 0.01), but was not significantly related to age in women (r = -0.25, NS). This is consistent with the previously described gender-specific reduction in hepatic oxidizing capacity association with increasing age. Thus oxaprozin is a slowly eliminated nonsteroidal anti-inflammatory agent that should be suitable for once daily or every other day administration.2

Three methods were established for the quantitative determination of oxaprozin. Potentiometry method is simple, rapid and accurate. The coefficient of variation was 0.1%. UV spectrophotometry can be applied to determination of oxaprozin. Its precision was less than potentiometry method’s. But the relative deviation was below 1%. In the method of HPLC, a chemical bonded phase column (WGC-C18), 10μm, 15cm ×4.6mm) was used. The mobile phase was methanolwater solution (75:25) and its flow rate was 1.0ml/min. The wavelength of the detection was 254nm. The results obtained by these three methods was in agreement. And the specificity of HPLC was the best. HPLC method can be used in the detection of impurities and the limit of the impurities. PLEASE NOTE: The full text of this publication is in Chinese.3

A rapid, simple and validated reversed-phase high-performance liquid chromatographic method has been developed for analysis of oxaprozin in pharmaceutical dosage forms. Oxaprozin was separated on an ODS analytical column with a 45:55 (v/v) mixture of acetonitrile and triethanolamine solution (5 mm , pH 3.5 ± 0.05, adjusted by addition of 85% phosphoric acid) as mobile phase at a flow rate of 2.0 mL min⁻¹. The effluent was monitored by UV detection at 254 nm. Calibration plots were linear in the range 160 to 240 μg mL⁻¹ and the LOD and LOQ were 14.26 and 41.21 μg mL⁻¹, respectively. The high recovery and low relative standard deviation confirm the suitability of the method for routine QC determination of oxaprozin in tablets.4

A high-performance liquid chromatographic method for the analysis of oxaprozin in the presence of ketoprofen (the internal standard) was developed. Sample preparation involved macro- and microextraction procedures. An octadecylsilane reversed-phase system with an acetonitrile–phosphate buffer (pH 3.9) mobile phase was used to separate the compounds from the extracted plasma components and the oxaprozin metabolites. Linear UV detector response over a wide concentration range resulted in rapid and reproducible quantitation.5

An HPLC method was established for the study on pharmacokinetics and bioequivalence of oxaprozin enteric tablet in healthy volunteers. Methods the oxaprozin in plasma was determined using HPLC method following a single oral dose of 400 mg of oxaprozin given respectively to 18 healthy male volunteers in an open randomized crossover design. The pharmacokinetic parameters and relative bioavailability were calculated to evaluate the bioequivalence of 2 preparations. Results AUC (0-240 h) of oxaprozin tested tablet and reference tablet were (2852.86? 871.00) and
The present research was aimed to develop a high performance liquid chromatography (HPLC) method to determine oxaprozin in plasma and to evaluate the bioavailability of two oxaprozin enteric coated tablets. A C18 column was used to separate the plasma after protein precipitation and the mobile phase was methanol-12. 5mmol/L ammonium acetate buffer solution (pH=3.0)(71: 29). The calibration curve was linear in the concentration range of 0. 50–70. 56 microg. mL⁻¹ and the intra and inter-day RSDs were less than 12. 33% and 10. 42% respectively. A single dose of 0. 4 g reference preparation or test preparation of oxaprozin enteric coated tablets was administered to 20 healthy volunteers according to a randomized crossover study. AUC0–→ 24h were (4 917. 44+/−629. 57) microg. h. mL⁻¹ and (4 604. 30+/−737. 83) µg/mL, respectively; Cmax were (52. 34+/−7. 68) microg. mL⁻¹ and (48. 66+/−4. 87) microg. mL⁻¹, respectively; Tmax were (18. 70+/−2. 27) h and (19. 30+/−1. 63) h, respectively; The relative bioavailability of test preparation was 94. 0%+/−13. 7%. The method is simple, rapid and selective for oxaprozin determination. There is no significant difference in the main pharmacokinetic parameters between the test formulation and reference formulation and the two formulations are in bioequivalence.

A method for the extraction of oxaprozin from equine urine and serum and its quantitation by high-performance liquid chromatography-ultraviolet detection is presented. Confirmation of oxaprozin in postadministration extracts was accomplished by gas chromatographic-mass spectrometric analysis of methylated extracts or liquid chromatography with tandem mass spectrometry daughter ion mass spectra of underivatized extracts. Daypro®, a formulation of oxaprozin, was administered orally at a dose of 4. 8 g to four standardbred mares. Urine and serum samples were collected to 120 h postadministration. Base hydrolysis of equine urine before extraction resulted in an increase in the amount of oxaprozin measured, an indication of conjugation by ester formation. The urinary elimination profiles of each horse were significantly different from each other with more than one peak in oxaprozin concentration before the 29–31-h collection time. After this collection time, the differences between the oxaprozin urinary concentrations of each horse follow each other more closely. The peak average urinary concentrations of oxaprozin were 25.1 and 17.0 µg/mL, respectively; Cmax were (52. 34+/−7. 68) microg. mL⁻¹ and (48. 66+/−4. 87) microg. mL⁻¹, respectively; Tmax were (18. 70+/−2. 27) h and (19. 30+/−1. 63) h, respectively; The relative bioavailability of test preparation was 94. 0%+/−13. 7%. The method is simple, rapid and selective for oxaprozin determination. There is no significant difference in the main pharmacokinetic parameters between the test formulation and reference formulation and the two formulations are in bioequivalence.

Quantitative aspects of high-performance liquid chromatography with a column-switching system (CSS–HPLC) and capillary electrophoresis (CE) were investigated for the determination of ibuprofen in plasma. For CSS–HPLC, 100 µl of plasma was directly injected onto the column system for the three separation steps: (1) deproteinization and fractionation of plasma samples with a polymer-coated mixed-function phase column, (2) concentration with an intermediate column and (3) final separation with a main column. For CE, a mixture of 50 µl.

Simple, rapid, selective and sensitive HPLC method was developed and validated for the determination of Oxaprozin from human plasma. The drug was extracted with ethyl tertiary butyl methyl ether. Oxaprozin was measured in plasma using a validated HPLC method with UV detector at 240nm chromatographic peaks were separated on 5µm inertsil, C18 column (4.6 x250mmx5µm) using 40: 60 v/v Phosphate buffer pH3, Acetonitrile as mobile phase at a flow rate of 1 mL/min. The chromatograms showed good resolution and no interference from plasma. The retention time of Oxaprozin and internal standard (Nevirapine) were approximately 7.7±0.05 min and 3.4±0.03 min respectively. The mean recovery from human plasma was found to be above 50%. The method was linear over the concentration range of 0.78 to 100µg/mL with coefficient of correlation (r2) 0.9983. Both intraday and interday accuracy and precision data showed good reproducibility. This method was successfully applied to pharmacokinetics studies. An HPLC procedure with UV detection has been developed for the quantitation of flurbiprofen in rat plasma. The drug and the internal standard (oxaprozin) were extracted from rat plasma with cyclohexane and quantitated using a reverse-phase C18 column. The chromatograms were completely free from interfering peaks, and the retention times of the flurbiprofen and the internal standard were 3.8 min and 5.4 min, respectively. Calibration plots were linear over the concentration range of 0.1 - 30µg/mL of flurbiprofen with the correlation coefficients all higher than 0.999. The mean intra-day precision and accuracy among three replicate sets of assay were 4.74% and 3.73%, respectively. The...
mean inter-day precision and accuracy over three days were 5.08% and 4.26%, respectively. The mean recoveries over the entire calibration range were 93.1% for the drug and 90.7% for the internal standard. The limit of detection for flurbiprofen was 1.0ng/mL. The method was simple, reliable and accurate for the quantitation of flurbiprofen in rat plasma13.

2.2. UV Estimation

Simple, sensitive, spectrophotometric method in UV region has been developed for the determination of oxaprozin in bulk and tablet dosage form. Solution of oxaprozin in 0.1 N NaOH shows maximum absorbance at 285 nm with apparent molar absorptivity of 1.3082 x 104 L/mol cm. Beer’s law was obeyed in the concentration range of 2-20 μg/mL with 0.9992 as and the slope, intercept were 0.0118, 0.04377, respectively. Results of the analysis were validated statistically and by recovery studies (100.21±0.8709). Result of percentage recovery and placebo interference shows that that the method was not affected by the presence of excipients which proves suitability of the developed method for the routine estimation of oxaprozin in bulk and solid dosage form12.

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Epidemiology and public health research relating to solar ultraviolet (UV) exposure usually relies on dosimetry to measure UV doses received by individuals. However, measure mtermsors affect each dosimetry measurement by unknown amounts, complicating the analysis of such measurements and their relationship to the underlying population exposure and the associated health outcomes. This paper presents a new approach to estimate UV doses without the use of dosimeters. By combining new satellite-derived UV data to account for environmental factors and simulation-based exposure ratio (ER) modelling to account for individual factors, we are able to estimate doses for specific exposure periods. This is a significant step forward for alternative dosimetry techniques which have previously been limited to annual dose estimation. We compare our dose estimates with dosimeter measurements from skiers and builders in Switzerland. The dosimetry measurements are expected to be slightly below the true doses due to a variety of dosimeter-related measurement errors, mostly explaining why our estimates are greater than or equal to the corresponding dosimetry measurements. Our approach holds much promise as a low-cost way to either complement or substitute traditional dosimetry. It can be applied in a research context, but is also fundamentally well-suited to be used as the basis for a dose-estimating mobile app that does not require an external device15.

Quantitative aspects of high-performance liquid chromatography with a column-switching system (CSS–HPLC) and capillary electrophoresis (CE) were investigated for the determination of ibuprofen in plasma. For CSS–HPLC, 100 μl of plasma was directly injected onto the column system for the three separation steps: (1) deproteinization and fractionation of plasma samples with a polymer-coated mixed-function phase column, (2) concentration with an intermediate column and (3) final separation with a main column. For CE, a mixture of 50 μl 16.

Direct detection of drugs in the blood contributes to the study of pharmacokinetics, whereas the low-concentration blood drug makes this goal challenging. Here, silver nanoparticles (AgNPs) are used for direct detection in the blood environment. The finite element method is used to study the electric field enhancement of AgNPs in the blood environment. We study the Raman enhancement factors associated with AgNPs and study the effects of parameters such as the wavelength, medium environment, and nanoparticle distribution on near-field enhancement. The method for directly detecting oxaprozin (OXA) drug in the blood of mice is reported, which is based on surface-enhanced Raman
The complexing, solubilizing and amorphizing abilities toward oxaprozin (a poorly water-soluble anti-inflammatory agent) of some β-cyclodextrin derivatives (hydroxypropyl-βCd, heptakis-2,6-di-O-methyl-βCd (DIMEB) amorphous randomly substituted methyl-βCd (RAMEB) and semi-crystalline methyl-βCd (CRYSMEB)) were investigated and compared with those of natural (α-, β-, γ-) cyclodextrins. The role of both the cavity size, the amorphous or crystalline state and the presence and type of substituent on the ability of cyclodextrins in establishing effective interactions with the drug has been evaluated. Equimolar drug-cyclodextrin solid systems were prepared by blending, kneading, co-grinding, sealed-heating, coevaporation, and colyophilization. Drug-carrier interactions were studied in both the liquid and solid state by phase-solubility analysis, differential scanning calorimetry, X-ray powder diffractometry, FT-IR spectroscopy and scanning electron microscopy. βCd showed the best performance among the natural Cds, indicating that its cavity was the most suitable for accommodating the drug molecule. The presence of substituents on the rim of the βCd cavity significantly improved its complexing and solubilizing effectiveness towards the drug, and methylated derivatives were better than the hydroxy-propylated ones. The amorphous nature of the partner was also important: among the examined methyl-derivatives, RAMEB proved to be the most effective in performing solid state interactions and in improving drug wettability and dissolution properties.

The complexing, solubilizing and amorphizing abilities of AgNPs with a diameter of 15 nm and further concentrated them as a SERS substrate to achieve low-concentration OXA solution detection in blood and aqueous environments. The minimum detection limit in the aqueous environment is 10–6 M, and the detection limit in the blood is 10–4 M (29.32 μg/mL), which is less than the peak blood drug concentration in clinical applications. Further analysis shows that OXA in the blood can be directly detected by SERS because of the characteristic peak of 1025 cm−1, and the corresponding attribution is the C–C–C plane vibration. The numerical simulation of AgNPs and the detection of OXA solution in the blood environment indicate that SERS has a good application prospect in low-concentration blood drug detection.

2.3. Colorimetry

The influence of l-arginine on the complexing and solubilizing power of randomly-methylated-β-cyclodextrin (RameβCD) towards oxaprozin, a very poorly soluble anti-inflammatory drug, was examined. The interactions between the components were investigated both in solution, by phase-solubility analysis, and in the solid state, by differential scanning calorimetry, FTIR and X-ray powder diffractometry. The morphology of the solid products was examined by Scanning Electron Microscopy. Results of phase-solubility studies indicated that addition of arginine enhanced the RameβCD complexing and solubilizing power of about 3.0 and 4.5 times, respectively, in comparison with the binary complex (both at pH ≈ 6.8). The effect of arginine was not simply additive, but synergistic, being the ternary system solubility higher than the sum of those of the respective drug-CD and drug-arginine binary systems. Solid equimolar ternary systems were prepared by physical mixing, co-grinding, coevaporation and kneading techniques, to explore the effect of the preparation method on the physicochemical properties of the final products. The ternary co-ground product exhibited a dramatic increase in both drug dissolution efficiency and percent dissolved at 60 min, whose values (83.6 and 97.1, respectively) were about 3 times higher than the sum of those given by the respective drug-CD and drug-arginine binary systems. Therefore, the ternary co-ground system with arginine and RameβCD appears as a very valuable product for the development of new more effective delivery systems of oxaprozin, with improved safety and bioavailability.

The poor physicochemical properties like low solubility and low dissolution rate of rosuvastatin calcium remain as an obstruction for formulation development. In the present investigation, we explore the evolution of rosuvastatin cocrystal, which may offer the synergetic physico-chemical properties of the drug. Cocrystal crafting depends on two possible intermolecular interactions, heteromeric and the homomeric selection of compounds with complementary functional groups are contemplated as a possible cause of supramolecular synths in cocrystal formation. Specifically, cocrystals of rosuvastatin with L-asparagine and L-glutamine with molar ratio (1:1) were fabricated by using slow solvent evaporation and solvent evaporation techniques. Novel cocrystals of rosuvastatin-asparagine (RSC-C) and rosuvastatin-glutamine (RSC-G) cocrystals obtained by slow solvent evaporation were utilized for preliminary investigation and further scale-up was done by using the solvent evaporation technique. The novel cocrystals showed a new characteristic of powder X-ray diffraction, thermograms of differential scanning calorimetry, 1H liquid FT-NMR spectra, and scanning electron microscopy. These results signify, the establishment of intermolecular interaction within the cocrystals. In both the novel cocrystals, rosuvastatin was determined to be engaged in the hydrogen bond interaction with the complementary functional groups of L-asparagine and L-glutamine. Compared with the pure rosuvastatin, RSC-C and RSC-G cocrystal showed 2.17-fold and 1.60-fold improved solubility respectively. The dissolution test showed that the RSC-C and RSC-G cocrystal exhibited 1.64-fold and 1.45-fold higher dissolution rate than the pure rosuvastatin in pH6.8 phosphate buffer respectively. Modulation in the chemical environment, improvement in the solubility and dissolution rate demonstrated the benefit of co-crystallization to improve the physicochemical properties of the drug.

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2.4. Hydrotropic Methods

The combinatorial chemistry and high throughput screening increases the solubility of poorly water soluble compounds. The most challenging task in development of a formulation is the solubility of drug, availability at the site of action and stability of drug. Aqueous solubility of any therapeutically active substance is a key property as it governs dissolution, absorption and thus the in vivo efficacy. Among all newly discovered chemical entities about 40% drugs are lipophilic and these drugs are rejected by the pharmaceutical industry and will never benefit a patient because of its poor bioavailability due to low water solubility and/or cell membrane permeability. Drug efficacy can be severely limited by poor aqueous solubility and some drugs also show side effects due to their poor solubility. This article reviews various methods used for improving the solubility of hydrophobic drugs and improve the drug release profiles which are exhibited by such formulations for poorly soluble drugs21.

2.5. Voltammetry

Square wave voltammetry (SWV) was selected as an alternative technique to study the release of PX from the carrier system. This technique allowed determine the entrapment efficiency and the release profile of the NLCs. The study was carried out in in vitro condition using a Franz diffusion cell and an artificial cellulose nitrate membrane. The NLCs showed a 100% encapsulation efficiency and a PX prolonged release, releasing the 60% of the incorporated drug in 120 h. From the SWV study, it was also possible to understand the release kinetic mechanism of the proposed carrier system22.

In this article, the interaction between [(η6-p-cymene) Ru (benzaldehyde-N (4)-phenylthiosemicarbazone) Cl] Cl anticancer drug and human serum albumin (HSA) was investigated systematically under physiological conditions by using some spectroscopic methods (UV-vis absorption spectroscopy, fluorescence spectroscopy, FT-IR spectroscopy, and CD spectroscopy), mass spectroscopy and cyclic voltammetry. The experimental results indicated that this anticancer drug could quench the intrinsic fluorescence of HSA through static quenching mechanism. The Stern–Volmer quenching model has been successfully applied, and the Stern–Volmer quenching constants together with the modified Stern–Volmer quenching constants at different temperatures were also calculated. The corresponding thermodynamic parameters ΔH, ΔG and ΔS were also calculated. The binding of this anticancer drug and HSA resulted in the formation of drug–HSA complex, and the electrostatic interaction played a major role in the complex stabilization. The distance r between the donor (HSA) and the acceptor (drug) was obtained through fluorescence resonance energy transfer theory. Competitive experiments indicated that the binding site of this anticancer drug to HSA was located at site I. The results of synchronous fluorescence spectra, three-dimensional fluorescence spectra, FT-IR spectra and CD spectra indicated that the microenvironment and the conformation of HSA were changed noticeably due to the presence of this anticancer drug. The results of mass spectra and cyclic voltammetry further confirmed the interaction between HSA and this anticancer drug. These results indicated that the biological activity of HSA was dramatically affected by the [(η6-p-cymene) Ru (benzaldehyde-N (4)-phenylthiosemicarbazone) Cl] Cl anticancer drug23.

The aim of this study was to explore the efficiency of ephedrine binding to human serum albumin (HSA) as a protein model using spectroscopic, electrochemical, and molecular docking methods. A reduction in UV absorbance at 280 nm of HSA was attributed to the interaction between ephedrine and HSA. The apparent binding constant (Kapp) values at different temperatures were about 104 M−1, which showed high affinity of ephedrine for HSA. The calculated negative enthalpy change (ΔH) and entropy change (ΔS) values suggested that the binding process was mainly driven by van der Waals force and hydrogen bonds. The negative value of free energy change (ΔG) indicated that the interaction process was spontaneous. The results of cyclic voltammetry (CV) further confirmed the high affinity of ephedrine for HSA with an association constant of 2.73 ± 0.17 × 104 M−1 at room temperature. Furthermore, molecular docking results revealed that ephedrine bound to site I in subdomain IIA via 2 hydrogen bonds with Phenylalanine 211 (Phe211) and Alanine 215 (Ala215) of HSA, and that Arginine 218 (Arg 218), Lysine 199 (Lys 199), and Serine 202 (Ser202) residues became involved in electrostatic interactions with ephedrine. Also, Leucine 198 (Leu198), Phe211, Tryptophan 214 (Trp214), Leu238, and Histidine 242 (His242) residues were responsible for the stability of the complex via hydrophobic interactions. Attenuated total reflection-Fourier transform infrared (ATR-FTIR) spectroscopy was used to investigate the conformational changes of HSA during the interaction of ephedrine and HSA24.

A rapid, selective and sensitive analytical method for the simultaneous determination of 16 nonsteroidal anti-inflammatory drugs (NSAIDs) in human plasma was carried out using Oasis HLB solid-phase extraction (SPE), followed by reversed-phase high-performance liquid chromatography and quadrupole mass spectrometry with electrospray ionization operated in the negative ion mode. The recoveries of NSAIDs from human plasma by SPE were greater than 76.7%. The use of a short column packed with small particles enabled rapid and simultaneous determination within 7 min. The detection limits for the NSAIDs were 0.01–0.9 μg/ml using the selected ion monitoring mode25.
3. Conclusion
The collected methods are various analytical methods for the estimation of oxaprozin is a non steroidal anti-inflammatory drug. A few HPLC methods have been for estimation oxaprozin in biological fluids. UV and other analytical methods have been reported for the literature of estimation of oxaprozin.

Compliance with ethical standards

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Disclosure of conflict of interest
No conflict of interest.

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