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From A Regulatory Standpoint, Clinical Pharmacokinetics: Existing Requirements and Future Views

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Introduction

Aside from typical pharmacokinetic studies in healthy volunteers, patients, and special subgroups, well-designed controlled studies using a wide range of dosages are required to produce credible dose-response curves for therapeutic and harmful e ects. Lower doses o en have a better risk/bene t ratio than those suggested. In high dose/concentration scenarios, secondary pharmacology of the drug and its active metabolites must be characterised in order to determine safety (adverse reactions and pharmacokinetic and pharmacodynamic drug-drug interactions) [1].

e enzyme systems responsible for a drug s metabolism must be identi ed, and then rational research of drug-drug and drug-disease interactions must be conducted, both in terms of e cacy and safety. During all phases of the drug s clinical development, factors responsible for changes in the functional expression of this enzyme system must be identi ed, and the safety and e cacy implications of these ndings at the interethnic, inter-, and intraindividual levels must be thoroughly investigated. As a result, patient subgroup-speci c dose regimens should be carefully developed to maximise the risk/bene t ratio for all patients [2-4].

Review

Because drugs act in a chiral environment, their pharmacokinetics and pharmacodynamics di er dramatically between enantiomers. It s important to look into the possibilities of interactions between a drug s enantiomers as well as enantioselective interactions. ese should be thoroughly explored, and the choice to market a racemic combination or one of its enantiomers must be supported by scienti c evidence.

drug chirality now provide compelling reasons for bioactivation, pharmacogenetics, and stereochemical factors to be addressed in pharmacokinetic studies during drug development. Capecitabine is one of the fuoro pyrimidine anticancer agents which is extensively used in the management of colorectal cancer. We have noticed a discrepancy between the doses we are using in our patients and the recommended dosing regimen. Thus, this study aims to assess the pharmacokinetic parameters of capecitabine and its metabolites in colorectal cancer patients and report some clinical outcomes.

which included physical examination, electrocardiogram (ECG) monitoring, chest X-ray test, and laboratory investigations (urinalysis, haematology, and serum biochemistry, serology, and pregnancy status) were carried out to con rm the eligibility of study participants. Screening and recruitment of study participants continued until

in uenced by genetic variants encoding essential drug-metaboli ing en ymes a er delivery. is article summarises recent case studies and examples of using pharmacokinetic screening approaches to reduce the nancial and ethical burden of recruiting larger numbers of subjects in bioequivalence trials to perform pharmacokinetic studies for formulations of highly variable drug products without expanding bioequivalence acceptance limits [8].

Pharmacokinetic simulation was performed to predict the pharmacokinetic pro le of Sinococuline on Days 03, 05, 08 and 09 at 200, 400, 600 and 800 mg TID doses of AQCH. Individual plasma concentration data of Sinococuline at 100 mg dose was used for model development of pharmacokinetic simulation. e simulation was done using Phoenix Modelling by Phoenix Win Nonlin Version 8.2 using compartmental modelling approach. A total of 1000 iterations were used during prediction of pharmacokinetic pro le for di erent dose levels [9]. e list of adverse events following active treatment of AQCH tablets or placebo is listed in . AQCH tablets were well tolerated in all the 5 cohorts. ere were no clinically signi cant ndings in the vital signs assessment, 12-lead ECG recording or the laboratory tests in any of the subjects in the study. No subject had a maximum on-treatment . AQng Pr placrts. ere wers