# Bioequivalence evaluation of the brand and generic Cinacalcet tablets in Saudi markets

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## INTRODUCTION

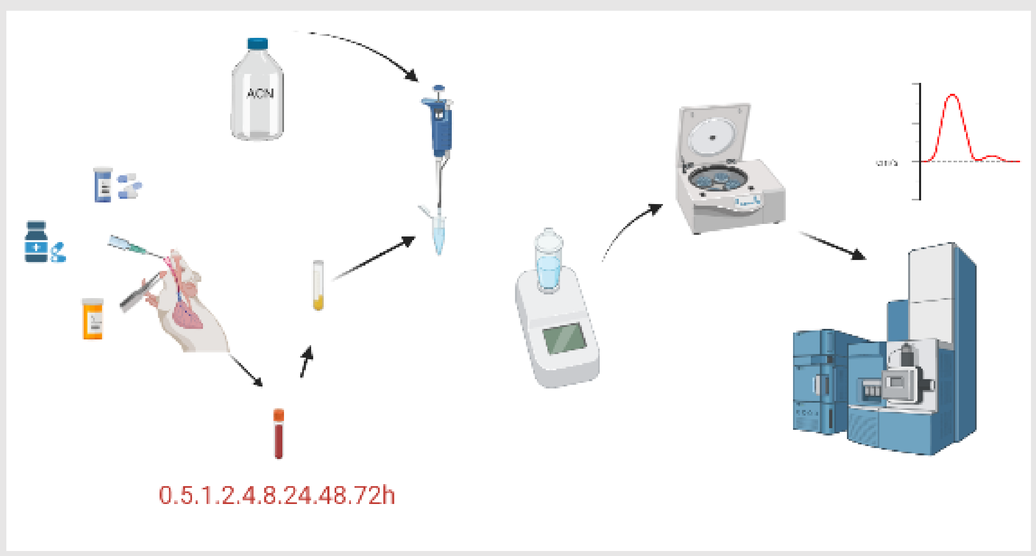
The Cinacalcet Hydrochloride work to increase the sensitivity of calcium ,that way decreasing parathyroid hormone (PTH) secretion. The Saudi Pharmaceutical Markets has developed generic alternatives to the reference brand of Cinacalcet tablets . The lacking of bioequivalence evaluations of generic Cinacalcet tablets in Saudi Market make it valuable to evaluate them. Therefore, in this study we evaluated the bioequivalence of Cinacalcet tablets in Saudi Market by assessing the pharmacokinetics (PK) parameter in Wistar rats.

## OBJECTIVES

To evaluate the rat plasma pharmacokinetics (PK) parameter of Cinacalcet brand versus two generic tablets in Saudi market in order to ensure their bioequivalence.

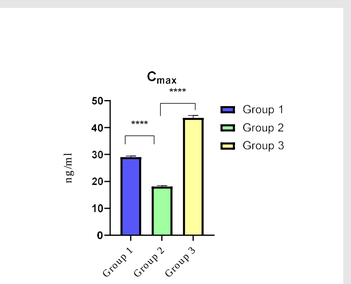
## METHODS

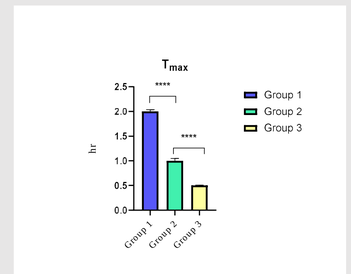
Validation of analytical procedure was performed complying with ICH guideline. PK Parameter in different three groups of rat after a single oral administration of Cinacalcet (brand or generic) were determined from plasma drug concentrations at different time points post dose using ultra-performance liquid chromatography time of flight mass spectrometry (UPLC-TOF/MS).

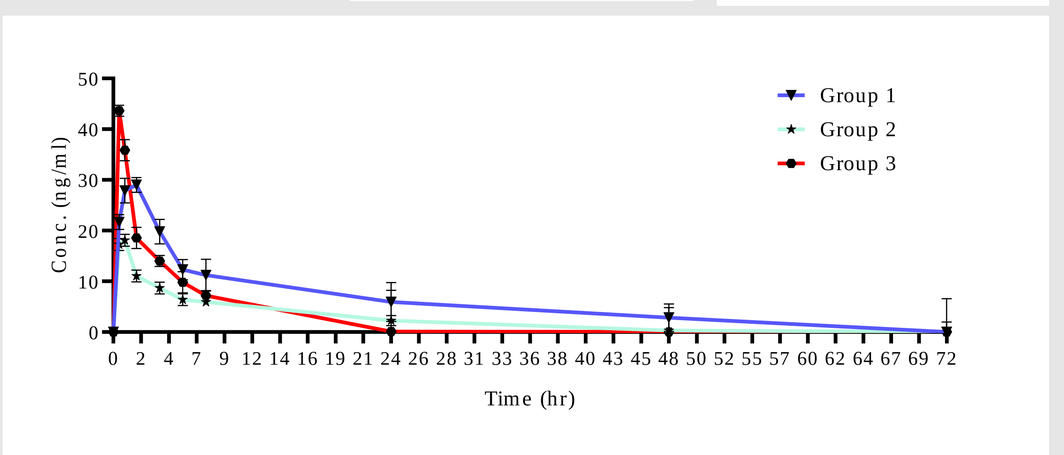



## RESULTS

Generic agents group1 and group 3 shows a higher values in $c_{max}$ (29.00, 43.65) ug/ml , $AUC_{0-\infty}$( 411.34, 193.21) , $T_{1/2}$ (8.28, 9.22) hours respectively ,along with significant decrease in clearance of both agents Cl(0.024, 0.051) ug/ml respectively compared to the reference group2 $c_{max}$ (18.09) ug/ml , $AUC_{0-\infty}$( 175.55) , $T_{1/2}$ (7.08) hours Cl(0.057) ug/ml.




## DISCUSSION & CONCLUSION

The present study prove a significant bioequivalent variations among the test generic products compared to the reference products . Our results indicates a PK alterations, safety and efficacy recommended to be evaluated. Accordingly, it might be of clinical importance.

## REFERENCES