maximum plasma concentration (max); time to reach Cmax (tmax); last measurable plasma concentration (Clast); area under the plasma concentration–time curve (AUC) from time zero to time of last measurable plasma concentration (AUClast), calculated according to the trapezoidal rule; AUC from time zero to infinity (AUC.), calculated using the equation: AUC.The term AE also applied to laboratory findings or results of other diagnostic procedures that were considered to be clinically relevant (e.g., required unscheduled diagnostic procedures or treatment measures or withdrawal from the study), unless directly related with the underlying disease of the participant (i.e., severe renal impairment).An AE was defined as any unfavorable and unintended sign (including an abnormal laboratory find–ing), symptom or disease, temporally associated with the use of the medicinal product, regardless of its nature, intensity, seriousness, or presumed relationship (causality) to the product or experimental procedure used.QTc intervals were calculated using Fridericia's (QTcF) and Bazett's (QTcB) correction formulas [23).Vital signs (temperature, respiratory rate, supine/standing pulse rate, systolic and diastolic blood pressure, and bodyweight) were recorded daily.Routine hematology, biochemistry, and urinalysis .were conducted at screening, pre–dose, and 72 h post–dose