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Original Research Article

PLASMA KINETIC PARAMETERS OF MEDICINAL SYNTHETIC ALUMINIUM MAGNESIUM SILICATE IN BROILERS

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ABSTRACT

Despite the volume of research on the medical relevance of medicinal synthetic aluminium magnesium silicate (MSAMS), there is no documented evidence regarding its absorption, distribution, metabolism or excretion in either humans or animals. To provide experimental evidence that MSAMS is absorbable, thus, can be used to treat systemic infections, thirty eighty (38) broilers which were raised from day old till they were six weeks old were drenched a single dose of 50 mg/kg MSAMS orally. Blood was collected from each chick post treatment (PT) at: 0.25, 0.5, 1, 2, 3, 6, 9, 12, 24, 36 and 48 hours, for evaluation of plasma-MSAMS concentrations. Means of plasma MSAMS concentrations in the broilers varied significantly ($P \leq 0.05$) between each time interval from 0 h (before drug administration: 0.51 ± 0.12) through time 0.25 h PT (0.97 ± 0.13) to 48 h PT (1.23 ± 0.15) with maximum concentration (Cmax: 1.87 ± 0.14) recorded at 0.5 h PT. The pharmacokinetic parameters recorded were Tmax (0.5h), AUC_{0-t} (59.72 ± 5.23), $AUC_{0-\infty}$ (195.68 ± 28.4), T1/2α (h) (0.201 ± 0.024), β (1/h) (0.0090 ± 0.0012), T1/2β (h) (76.68 ± 12.3) and Vd (28.3 ± 4.6). The results showed that the MSAMS is absorbable.

Keywords: broilers, MSAMS, plasma kinetics,

INTRODUCTION

Pharmacokinetics is the study of drug movement within the body (Saganuwan, 2012). It is used to predict the concentration or amount of drug in different organs/tissues over a period of time. Pharmacokinetic processes are absorption, distribution, metabolism and elimination (ADME) (Saganuwan, 2012). The MSAMS is a formulation of aluminium magnesium silicate (AMS), an approved medicine (Vanderbilt, 2012) to which dextrose monohydrate (a simple sugar) was added. The simple sugar facilitates transport of AMS nanoparticles across mucous membranes (Murray, 2000).

AMS is an odourless, tasteless, and off-white to creamy white, soft, slippery small flakes or fine micronized powder or granules (Sánchez-Martín *et al*., 2008; NCBI, 2023). Molecules of AMS (a clay particle) are 0.96 nanometre thick and some hundred nanometres across (Scenihr, 2001; Vanderbilt, 2012). AMS is a polymeric complex of aluminium, magnesium, silicon, oxygen and water (Sposito *et al*, 2023). It has negative and positive charges on its surface and edges respectively (Perrott, 1977; Matocha, 2017). It is marketed as Veegum® or Pyropes® in the pharmaceutical industry (Vanderbilt, 2012). In pharmaceutical industries, AMS is used as an adsorbent, stabilizing, suspending, viscosity-enhancing, anticaking, opacifying, tablet binder and capsule disintegrant agent (Vanderbilt, 1992; Wai *et al*., 1996; Wenninger *et al*., 2000; Merck Index, 2013; NCBI, 2023).

Ezeibe (2012) reacted two medicinal minerals found in many countries including Nigeria; Aluminium silicate ($Al_4(SiO_4)_3$) and Magnesium silicate (Mg_2SiO_4); to get MSAMS [$Al_2Mg_3(SiO_4)_3$] and expressed the reaction with an equation: $\{Al_4(SiO_4)_3 + 3Mg_2SiO_4 \rightarrow 2Al_2Mg_3(SiO_4)_3\}$. To this formulation, Ezeibe (2012) added dextrose monohydrate to act as a carrier and named the formulation, MSAMS. The MSAMS is a nano-medicine

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and has proved effective against viral diseases and abnormal-cell diseases in both man and animals (Ezeibe *et al*, 2022). It has adjuvant efficacy (Udom 2018, Onyeachonam, 2022, Akpan 2023; Ogbonna 2023). Despite these findings, pharmacokinetic parameters of MSAMS remain unstudied. There is no documented evidence regarding its absorption, distribution, metabolism and excretion in either humans or animals. Therefore, this study was designed to investigate the plasma kinetics of MSAMS in broilers.

MATERIALS AND METHODS

The drug used for the study, MSAMS, was supplied by Ezeibe (2012: NG/P/2012/639).

EXPERIMENTAL ANIMALS

Thirty eight (38) day-old broiler chicks were raised on deep litter until they were six weeks old. Feed and water were provided for them, *ad libitum*. They were vaccinated against Newcastle and Gumboro diseases.

EXPERIMENTS

A single dose of 50 mg/kg MSAMS was administered orally to the chicks at six weeks of age. Fifteen minutes before the treatment and at 0.25, 0.5, 1, 2, 3, 6, 9, 12, 24, 36 & 48 hours post treatment (PT), 2mls of blood were collected into sample bottles containing ethylene diamine tetra acetic acid from each of three randomly selected chicks. The blood samples were centrifuged at 4000 rpm for 10 minutes and the plasma obtained were stored at - 10°C until assayed.

Plasma (1 ml) samples (0.5–1 g) were digested using wet acid digestion. Briefly, 5 ml of concentrated nitric acid (HNO_3) was added to the blood sample and heated at 80–120°C until a clear solution was obtained. The digests were cooled, filtered where necessary and diluted to a known volume (50 ml) using deionized water (AOAC, 2019). Standard stock solutions of aluminium, magnesium and silicon were prepared and serially diluted to obtain working standards of varying concentrations (0, 1, 2, 5, and 10 ppm). These standards were used to generate calibration curves for quantification.

DETERMINATION OF ALUMINUM AND MAGNESIUM

Aluminium and magnesium concentrations were determined using an atomic absorption spectrophotometer (AAS) (PerkinElmer). Appropriate hollow cathode lamps were used and the instrument was operated at wavelengths of 309.3 nm for aluminium and 285.2 nm for magnesium using an air–acetylene flame. The instrument was calibrated using blank and standard solutions before sample analysis.

Absorbance readings were obtained and concentrations of metals in plasma and tissue samples were calculated using the calibration curve and expressed as mg/L (plasma).

Calibration curves were prepared using standard solutions and sample concentrations were calculated as described by AOAC (2019).

DETERMINATION OF SILICATE (COLORIMETRIC METHOD)

Silicate concentration in plasma samples was determined using the molybdenum blue colorimetric method AOAC (2019).An aliquot of the digested sample was taken, and ammonium molybdate reagent was added under acidic conditions to react with silicate, forming a yellow silicomolybdic acid complex. This complex was subsequently reduced using ascorbic acid to form a blue-coloured complex (molybdenum blue) (AOAC, 2019). Intensity of the blue colour, which is directly proportional to the silicate concentration, was measured spectrophotometrically at a wavelength of approximately 810–820 nm. A calibration curve was prepared using standard silicate solutions, and the concentration of silicate in the samples was determined from the curve.

Metal and silicate concentrations were calculated using calibration curves and appropriate dilution factors. Results were expressed as mg/L.

$$\text{Concentration in sample} = \frac{\text{AAS reading x dilution factor}}{\text{Sample weight or volume}}$$

DATA ANALYSIS

Pharmacokinetic parameters were determined using the non-compartmental method based on statistical moment's theory (Singh, 1999) and calculated using equations by Baggot (1977).

The data on plasma kinetics and Pharmacokinetic parameter were presented in graphical and tabular form and presented as Mean ± Standard Errors of Mean (SEM) and the means between each time interval compared by Repeated Analysis of Variance (ANOVA). Tested for significant differences were by Turkey Post hoc test and least significant difference was judged at 5% ($P \leq 0.05$: Daniel, 2010).

RESULTS

Mean plasma concentration of MSAMS of 0.966 ± 0.128 mg/L was obtained in the broilers drenched MSAMS at 0.25 hr PT. The plasma concentration increased to reach peak at 0.5 hr (1.87 ± 0.14 mg/L) and thereafter decreased to 1.23 ± 0.15 mg/L at 48 hr PT. Means of MSAMS varied significantly ($P \leq .05$) at multiple time intervals when compared to 0 hr as shown on Table I .

Pharmacokinetic parameters of MSAMS in broiler-chicks following a single oral administration at dose of 50 mg/kg body weights were Peak plasma concentration (Cmax) (1.87 ± 0.14 mg/L); Area under the plasma concentration versus time curve from 0 to time (AUC0-t) (59.72 ± 5.23 µg/ml.h); Area under the plasma concentration versus time curve from

0 to infinity (AUC0-∞) (195.68 ± 28.4 µg/ml.h); Absorption rate constant (α 1/h) (3.45 ± 0.42); Absorption half-life T1/2α (h) (0.20 ± 0.02 h); Elimination rate constant β (1/h) (0.01 ± 0.00 h); Elimination half-life (T1/2β: 76.68 ± 12.3 h); Mean residence time (MRT: 24.81 ± 2.8 h); Time to reach maximum plasma concentration (Tmax : 0.50 ± 0.00 h), Volume of distribution (Vd: 28.3 ± 4.6 L/Kg) and Total body clearance (Cl: 0.26 ± 0.04 L/kg/h) Table II and Figure I.

TABLE I: MEAN PLASMA CONCENTRATION OF MSAMS (MG/L) IN BROILERS AT DIFFERENT HOURS POST TREATMENT

TIME (hours)	MSAMS (mg/L)
0	0.51 ± 0.12^{c}
0.25	0.97 ± 0.13^{bc}
0.5	1.87 ± 0.14^{a}
1	1.18 ± 0.09^{bc}
2	0.95 ± 0.13^{bc}
3	1.44 ± 0.13^{ab}
6	1.35 ± 0.09^{ab}
9	1.21 ± 0.06^{b}
12	0.89 ± 0.04^{bc}
24	1.27 ± 0.20^{b}
36	1.42 ± 0.24^{b}
48	1.23 ± 0.15^{b}

TABLE II: PHARMACOKINETIC PARAMETERS OF MSAMS IN BROILERS FOLLOWING AN ORAL TREATMENT AT 50 MG/KG BODY WEIGHT

KINETIC PARAMETERS	MSAMS (MG/L)
Cmax (mg/L)	1.87 ± 0.14
Tmax (h)	0.50 (±0)
Ka (h^{-1})	3.45 ± 0.42
t½_abs (h)	0.20 ± 0.02
kel (h^{-1})	0.01 ± 0.00
t½_el (h)	76.68 ± 12.3
AUC0-48 (mg·h/L)	59.72 ± 5.23
AUC0-∞ (mg·h/L)	195.68 ± 28.4
CL/F (L/h/kg)	0.26 ± 0.04
Vd/F (L/kg)	28.3 ± 4.6
Vss/F (L/kg)	6.35 ± 1.05
MRT (h)	24.81 ± 2.8
F (%)	97.8 ± 14.2

Data are presented as means ± SEM; Cmax = maximum concentration; Tmax = time of maximum concentration; α = absorption rate constant; T1/2α = absorption half-life; β = elimination rate constant; T1/2β = elimination half-life; Vd = volume of distribution; Cl = total body clearance; MRT = mean residence time; AUC0-t = area under the plasma concentration vs time curve from 0 to time; AUC0-∞ = area under the plasma concentration vs time curve from 0 to infinite ; AUMC = Area under the moment curve.

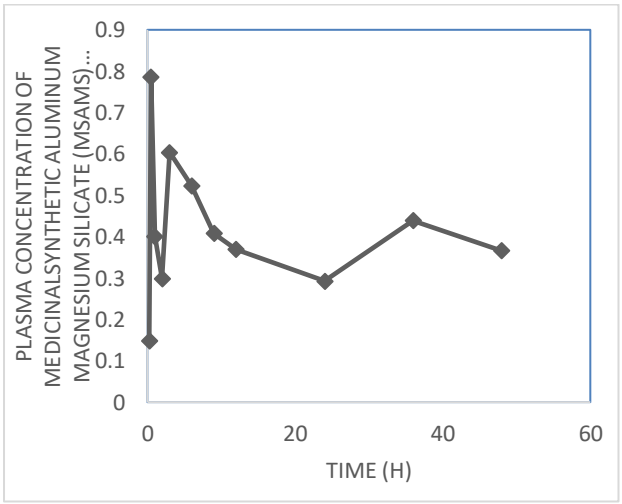

Figure I: Mean semi-log plasma concentrations of MSAMS in broilers following oral treatment with 50 mg/kg.

DISCUSSION

Pharmacokinetic profile of MSAMS in broilers undergoes a multi-compartmental model of elimination. The significant differences (P≤ 0.05) in mean plasma concentrations of MSAMS between the time intervals when compared with the concentration at time 0 suggests that MSAMS was rapidly absorbed, peaking at 0.5 h with sustained therapeutic levels through 48 h. The measurable levels of MSAMS

suggest that the medicine was carried from GIT of the broilers into systemic circulation by Dextrose monohydrate which was incorporated in the formulation. The results agree with Ezeibe (2012) who reported that incorporating Dextrose monohydrate in MSAMS formulation made it act systemically.

Sustained therapeutic levels of MSAMS in plasma of the broilers up to 48 hours PT indicates that MSAMS is not easily metabolized nor eliminated from the blood and that it could have high tissue binding affinity. The results agree with McGinity & Lach, (1977) who reported sustained-release of AMS.

Volume of distribution of MSAMS in broilers was 28.3 ± 4.6 L/kg which is very high according to magnitude of classification by NCBI, (2023) suggesting that MSAMS was extensively distributed to body tissues beyond plasma and extracellular fluid. Also, Vd of 28.3 ± 4.6 L/kg showed that MSAMS resides in tissues rather than in plasma and the fluctuations in plasma level of MSAMS that dropped at 2 and 12h (0.95 ± 0.13 and 0.89 ± 0.04) and came up again at 3 and 24 h (1.44 ± 0.13 and 1.27 ± 0.20) respectively indicates that MSAMS redistributes from tissues back into blood thus limiting overall clearance. It is a fact that the greater the volume of distribution, the longer the half-life of elimination (T1/2β) and the slower will the drug be eliminated from the body (Baggot, 1977).

Elimination half-life represents the time it takes for the plasma concentration of a drug to reduce to half of its original value after administration (Allan, 2024). It determines how frequently a drug should be administered to maintain therapeutic levels, meaning that drugs with short half-lives require more frequent dosing while those with long half-lives can be dosed less often (Allan, 2024). Elimination half-life of MSAMS is 76.68 ± 12.3 h in the present study which suggests slow clearance dominated by extensive tissue distribution. This prolonged elimination suggests that MSAMS could be taken once in three days.

The total body clearance is a reflection of the elimination of drugs from the body (Bourne 2010). The higher the concentration of a drug in plasma, the more the drug is presented for elimination. Thus, clearance is the coefficient of proportionality between plasma drug level and elimination (Bourne, 2010). The relatively low clearance (0.26 ± 0.04) observed in this study indicates slower elimination and prolonged systemic exposure of MSAMS. This low clearance also means longer duration of action of MSAMS and moderate drug exposure which is evidenced by the value, 59.72 ± 5.23 obtained as area under the curve to last measurable point (AUC_0-t). The AUC represents total systemic exposure to a drug from administration to infinity or to the last measurable point.

The value obtained in this study suggests that 50 mg/kg MSAMS produced good therapeutic threshold, supporting antimicrobial efficacy (time-dependent killing) (Bourne, 2011) and achieved excellent exposure without excessive accumulation to cause toxicity.

Mean residence time (MRT) is the average time a drug molecule stays in the body before elimination (Sobol & bailer, 2004). MRT of 24.81 ± 2.8 h suggests that MSAMS remain detectable in systemic circulation after a single oral administration for up to 24 hours or averaging one day. Although the mean resident time (24.81 ± 2.8 h) indicates that most of the drug is cleared within a day, the prolonged elimination half-life (76.68 ± 12.3 h) suggests the presence of a slower terminal elimination phase, where a fraction of the medicine remains in the body and is eliminated gradually.

MRT/t½ ratio of 0.32 confirms multi-compartmental behaviour of MSAMS with rapid distribution (Vd/F=28.3 L/kg) preceding slow elimination, distinguishing this pharmacokinetic profile from immediate-release formulations.

CONCLUSION

Plasma kinetic profile of MSAMS following a single oral dose of 50 mg/kg produced rapid absorption, measurable and sustained systemic exposure, and a relatively prolonged elimination phase. Therefore, MSAMS is absorbable and can be used to treat systemic infections that are sensitive to it.

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