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APPLICATION NUMBER:

206814Orig1s000

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

BIOPHARMACEUTICS REVIEW Office of New Drugs Quality Assessment			
Application No.:	NDA 206-814	Reviewer: Sandra Suarez Sharp, Ph.D.	
Division:	DCRP		
Applicant:	Pharma-Med, Inc.	Team Leader: Angelica Dorantes, Ph.D.	
Trade Name:	----	Supervisor (acting): Paul Seo, Ph.D.	
Generic Name:	Potassium Chloride Oral Solution	Date Assigned:	Feb 28, 2014
Indication:	Treatment of hypokalemia	Date of Review:	Oct 10, 2014
Formulation/strength	Oral Solution, 20 mEq/15 mL and 40 mEq/15 mL		
Route of Administration	Oral		
SUBMISSIONS REVIEWED IN THIS DOCUMENT			
Submission dates	Date of informal/Formal Consult	PDUFA DUE DATE	
Feb 27, 2014 Jul 7, 2014	Feb 28, 2014	Oct 23, 2014	
Type of Submission:	505(b)(2)		
Type of Consult:	Biowaiver Request		
SUMMARY OF BIOPHARMACEUTICS FINDINGS			
<p>Submission: Pharma-Med, Inc is seeking approval of Potassium Chloride Oral solution, USP, 20 mEq/15 mL and 40 mEq/15 mL for the treatment of patients with hypokalemia with or without metabolic alkalosis, (b) (4). This 505 (b)(2) application relies on the previous findings for NDA 019439 for Potassium Chloride Extended Release Tablet 20 mEq (Schering).</p>			
<p>Drug Product: The product under review is being proposed in two strengths, 20 mEq/15 mL and 40 mEq/15 ml. Both strengths have the same inactive ingredients, but differ in the amount of active ingredient (b) (4).</p>			
<p>Pursuant to 21 CFR 320.22(a), a waiver of the requirement for the submission of evidence measuring the in vivo bioavailability or demonstrating the in vivo bioequivalence of the drug product is included. In support of the biowaiver, published literature information on the bioavailability of unapproved oral solutions versus the approved extended release drug product is included this submission.</p>			
<p>Review: The biopharmaceutics review is focused on the evaluation and acceptability of the data supporting 1) the bridging between the formulations of the proposed oral solution and</p>			

the solutions used in the published BA studies (e.g., data from NDA 19123, NDA 19439), and 2) the proposed higher strength (Potassium Chloride Oral Solution, 40 mEq/15 mL).

Reviewer's Assessment

1. Bridging of Formulations between the Proposed Product and the Products Evaluated in the Published Literature

The Applicant is relying on the pharmacokinetic information from five articles to support their bioequivalence waiver request. These data are being reviewed by the OCP review team. These articles compared the systemic exposure of potassium chloride solutions to the extended release tablet formulation. It is noted that during the review cycle, the Applicant was requested to provide the components and composition of the potassium chloride oral solutions evaluated in the published BA studies to support the relative systemic exposure of their proposed product. The data provided showed that the differences in formulation are minor and it is expected that the systemic exposure will not be impacted (e.g., the difference excipient are known not to impact the systemic exposure).

Based on the clinical pharmacology, the results from the published literature show that the bioavailability of KCl, as measured by the cumulative urinary excretion of K⁺ over a 24 hour post dose period, is comparable across the liquid formulation and various types of modified release products. The OCP Reviewer concluded that the potential differences in rate of absorption of KCl from the solution formulation and modified release products may not be clinically relevant for K⁺ supplementation (*for details refer to the OCP review by Dr. Sabarinath in DARRTS*).

It should be noted that the proposed product submitted under a 505(b)(2) NDA does not appear to satisfy the criteria for a waiver of evidence of in vivo bioavailability under 21 CFR 320.22 (a). Specifically, the dosage form of the approved product is an extended release oral tablet and the product under review is an oral formulation; however, based 21 CFR 320.24(b)(6), the Applicant can rely on the literature information, provided the clinical pharmacology review team finds this information scientifically relevant. In addition, as per 505 (b)(2) regulations, bridging information demonstrating sufficient similarity between the proposed product and the listed drug or information can be obtained from published literature to justify reliance on the drug or literature for approval.

In conclusion, the provided overall information (formulation and PK) supports the bridging of the proposed product and the products used in the published publications and therefore the biowaiver for the proposed Potassium Chloride Oral Solution is granted.

2. Data Supporting the higher strength

Although the two proposed strengths are borderline on the requirement for formulation-composition proportionality, given that potassium chloride is a highly soluble and highly permeable drug substance and the drug product is in solution, this requirement may not be of clinical relevance for this drug product. In addition, the provided supporting literature includes data for the 40 mEq strength.

3. Risk Assessment Evaluation

Refer to the CMC review for the quality risk assessment table of this product. Given that the drug substance is highly soluble and the drug product is a stable solution for oral administration with high bioavailability, from the Biopharmaceutics perspective, the proposed Potassium Oral Solution is considered a low risk drug product.

RECOMMENDATION:

ONDQA-Biopharmaceutics had reviewed NDA 206-814 and its amendments submitted on Feb 28, 2014 and July 1, 2104. The provided formulation and PK information supports the bridging of the proposed product and the products used in the published pharmacokinetic literature and therefore a biowaiver for the proposed Potassium Chloride Oral Solution is granted.

From the Biopharmaceutics perspective, NDA 206814 for Potassium Chloride Oral Solution 20 mEq/15 mL and 40 mEq/15 mL is recommended for **APPROVAL**.

**Sandra
Suarez -A**

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BIOPHARMACEUTICS ASSESSMENT

BACKGROUND

Pharma-Med, Inc is seeking approval of Potassium Chloride Oral solution, USP, 20 mEq/15 mL, 40 mEq/15 mL for the treatment of patients with hypokalemia with or without metabolic alkalosis, (b) (4)

(b) (4) This 505 (b)(2) application relies on the previous findings for NDA 019439 for Potassium Chloride Extended Release Tablet 20 mEq (Schering).

CHEMISTRY

Drug Substance

Some key general properties for the drug substance are summarized in the Table 1 below.

Table 1. Physicochemical properties of KCl

Description	White crystalline or colorless solid (General Chemical)
Solubility	Solubility in water is (b) (4) (b) (4) Soluble in (b) (4) (b) (4)
Melting Point	(b) (4)
Partition Coefficient	(b) (4)
Polymorphism	No polymorphs listed (Refer to DMF (b) (4))
pKa	(b) (4)
Hygroscopicity	Hygroscopic
Density	1.984 g/cm ³
Refractive Index	(b) (4)

Potassium Chloride is reported as a BCS Class I drug and is therefore characterized as having a high solubility and high permeability.

Drug Product

The proposed potassium chloride oral solution, USP, 20 mEq/15 mL and 40 mEq/15 mL drug product strengths are a clear orange colored, orange flavored liquid, packaged in a (b) (4) white high density polyethylene (HDPE) bottle (b) (4). The fill volume for both is 473 mL.

The composition of the proposed oral solutions 20 mEq/15 mL and 40 mEq/15 mL and the function of the components are presented in Tables 2 and 3, respectively.

Table 2. Composition of Potassium Chloride Oral Solution, USP, 20 mEq/15 mL

Component	20 mEq/15 mL		Function
	(mg/15 mL)	(%w/v)	
Potassium Chloride, USP	(b) (4)	(b) (4)	Active
Glycerin, USP		(b) (4)	
Propylene Glycol, USP			
Methylparaben, NF			
Propylparaben, NF			
Sucralose, NF			
Sodium Citrate Dihydrate, USP			
Citric Acid, Anhydrous, USP			
Natural and Artificial Orange			
(b) (4)			
(b) (4)			
FD&C Yellow #6 (b) (4)			
Purified Water, USP			

Table 3. Composition of Potassium Chloride Oral Solution, USP, 40 mEq/15 mL

Component	40 mEq/15 mL		Function
	(mg/15 mL)	(%w/v)	
Potassium Chloride, USP	(b) (4)	(b) (4)	Active
Glycerin, USP		(b) (4)	
Propylene Glycol, USP			
Methylparaben, NF			
Propylparaben, NF			
Sucralose, NF			
Sodium Citrate Dihydrate, USP			
Citric Acid, Anhydrous, USP			
Natural and Artificial Orange			
(b) (4)			
(b) (4)			
FD&C Yellow #6 (b) (4)			
Purified Water, USP			

DATA SUPPORTING THE BIOWAIVER REQUEST

In accordance to 21 CFR 320.22(a), the Applicant has requested a waiver of the requirement for the submission of evidence measuring the in vivo bioavailability or demonstrating the in vivo bioequivalence of the proposed drug product. In support of the biowaiver, published literature information on the bioavailability of unapproved oral solutions versus the approved extended release drug product is included this submission.

According to the Applicant, since potassium chloride oral solution is rapidly and completely absorbed, the excipients used to manufacture the Potassium Chloride Oral

Solution, USP, 20 mEq/15 mL and 40 mEq/15 mL will not interfere with its absorption or bioavailability. In order to ensure similarity between the formulations used in the published PK data and the proposed product, the following comment was submitted to the Applicant during the review cycle:

- *Please provide a table comparing the formulation (components and composition) of your proposed drug product and formulations used in the PK references upon which you are relying. Please provide a justification for any difference between these formulations (proposed product and the oral solution formulations used in the PK references) with respect to concentration, inactive ingredients, pH, and osmolality.*

On a submission dated Jul 7, 2014, the Applicant responded that they utilized the (b) (4) a potassium chloride oral solution, 10% (20 mEq/15 mL) as the PK reference to support the proposed drug product. This reference drug was also utilized to support Schering's NDA, number 019439. The composition of (b) (4) is presented in Table 4 in comparison to the composition of the proposed drug product.

Table 4. Comparative Composition of the Formulations

Ingredients	Function	Pharma-Med, 20 mEq/15 mL		(b) (4) 10% (20 mEq/15 mL)	
		% w/v	mg/15 mL	% w/v	mg/15 mL
Potassium Chloride	API	(b) (4)			
Glycerin	(b) (4)				
Propylene Glycol					
Methylparaben					
Propylparaben					
Sucralose					
Sodium Citrate, Dihydrate					
Citric Acid Anhydrous					
Natural and Artificial Orange Flavor					
FD&C Yellow #6					
Purified Water, USP					
(b) (4)					

*While a flavoring agent is present in the (b) (4) formulation, the flavor is not known.

According to the Applicant, the osmolality of (b)(4) is not known. However, in an effort to determine the osmolality, a formulation was prepared containing the ingredients in (b)(4) outlined/used concentrations. The osmolality and pH of the formulation prepared and the proposed product are summarized in the table below.

Product	pH	Osmolality (moles/kg)
Proposed Drug Product	5.7	1.23
(b)(4)	4.8 theoretical	1.28 theoretical

As noted in Table 4 above, propylene glycol is present in the proposed product and not in the formulation evaluated in the published articles. Propylene glycol (b)(4) of the active ingredients. Given that potassium chloride is considered highly soluble (b)(4), the impact on the BA of the drug product is considered not significant. Therefore, from biopharmaceutics perspective the formulations can be considered similar and the conclusions drawn from the published literature by the OCP review team should not be affected by formulation differences.

According to the OCP Reviewer, the results from the published literature show that the bioavailability of KCl, as measured by the cumulative urinary excretion of K⁺ over a 24 hour post dose period, is comparable across the liquid formulation and various types of modified release products. The OCP Reviewer added that as expected, the KCl oral solution showed higher initial urinary excretion during the 0-6 hour period, reflecting rapid absorption, relative to the slow release products. Conversely, the slow release products such as microencapsulated tablets or wax-matrix tablets showed slightly higher urinary excretion of potassium during the later collection periods. The OCP reviewer concluded that the potential differences in rate of absorption of KCl from the solution formulation and modified release products may not be clinically relevant for K⁺ supplementation (*for specifics refer to OCP review by Dr. Sabarinath in DARRTS*).

It should be noted that the proposed product does not appear to satisfy the criteria for a waiver of evidence of in vivo bioavailability under 21 CFR 320.22 (a). Specifically, the dosage form of the approved product is an extended release oral tablet and the product under review is an oral formulation; however, based 21 CFR 320.24(b)(6), the Applicant can rely on the literature information provided the clinical pharmacology review team finds it scientifically relevant. In addition, bridging information demonstrating sufficient similarity between the proposed product and the listed drug or information can be obtained from published literature to justify reliance on the drug or literature for approval of the (b)(2) product. Refer to the clinical pharmacology review for conclusions/recommendation in terms of the acceptability of the literature data submitted to support the approval of this drug product.

DATA SUPPORTING THE APPROVAL OF THE HIGHER STRENGTH

Although the two proposed strengths are borderline on the requirement for formulation-composition proportionality, given that potassium chloride is a highly soluble and (b) (4) [REDACTED], this requirement may not be of clinical relevance. In addition, the provided supporting literature includes data for the 40 mEq strength.

REVIEWER'S OVERALL ASSESSMENT: ACCEPTABLE

The overall provided information (formulation and PK) supports the bridging of the proposed product and the products used in the published pharmacokinetic literature and therefore the biowaiver for the proposed Potassium Chloride Oral Solution is granted.

NDA 206814 for Potassium Chloride Oral Solution 20 mEq/15 mL and 40 mEq/15 mL is recommended for approval.

This review focuses on the published information from five relevant publications and the FDA approval package for NDA 019123, publicly available at Drugs@FDA. These provide bioavailability information for KCl from oral solution relative to other formulations (modified release dosage forms).

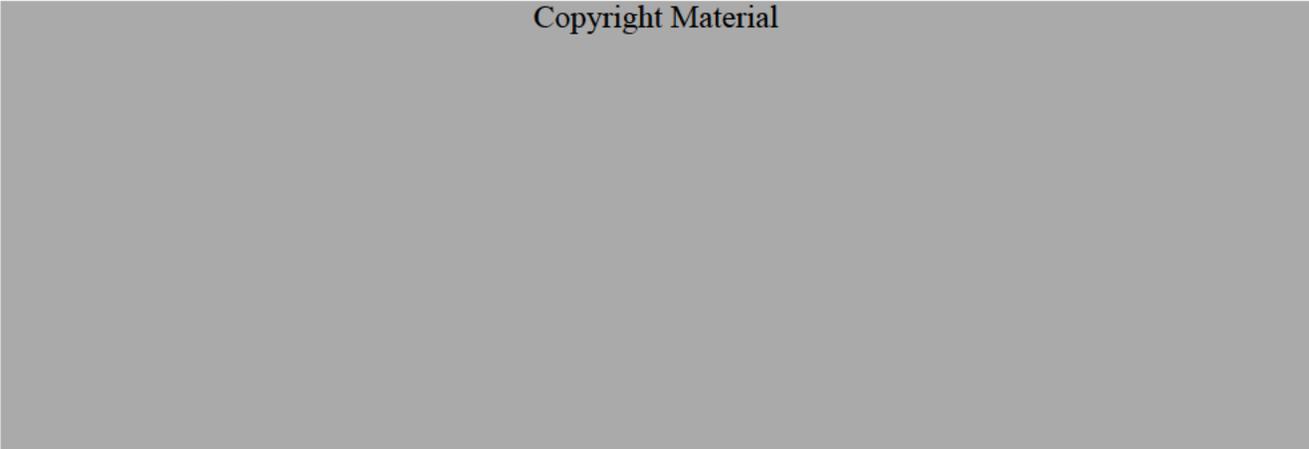
PUBLISHED CLINICAL STUDIES:

1. Publication by Melikian AP *et al.*¹

This study reported the urinary excretion of K⁺ in a four-period, four-treatment, cross-over study in 28 healthy male subjects. The four treatment arms were Control (no KCl administration), 40 mEq dose of suspension containing microencapsulated KCl, microencapsulated KCl capsule and KCl solution. Bioavailability of KCl was represented by cumulative amount of K⁺ excreted in urine for 24 and 48 hours post dose (See Table 1 below). Following the fourth dose, urinary excretion of K⁺ was measured more frequently within the inter-dosing interval. The cumulative amount of K⁺ excreted in urine over 24 hours after dosing is shown in Figure 1A.

Table 1. Urinary excretion of K⁺ (mEq). Values are Mean ± SD.

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(Source: Table 1, Melikian *et al.* 1988)

Excretion rates were estimated by dividing the amounts of K⁺ excreted during a urine collection interval by the duration of the collection interval. Significantly greater amounts of K⁺ were excreted in the first few hours after ingestion of the solution than after administration of the suspension or capsules (Figure 1B). Thereafter the rate of K⁺ excretion from the solution formulation decreased and by 4-8 hours was less than that from the suspension and capsule. After 8 hours, the rates of K⁺ excretion from the three formulations were similar.

¹ Melikian AP *et al.*, Bioavailability of potassium from three dosage forms: suspension, capsule and solution. *Journal of Clinical Pharmacology*. 1988, 28: 1046-1050

A. Cumulative Amount Excreted

B. Urinary Excretion Rate

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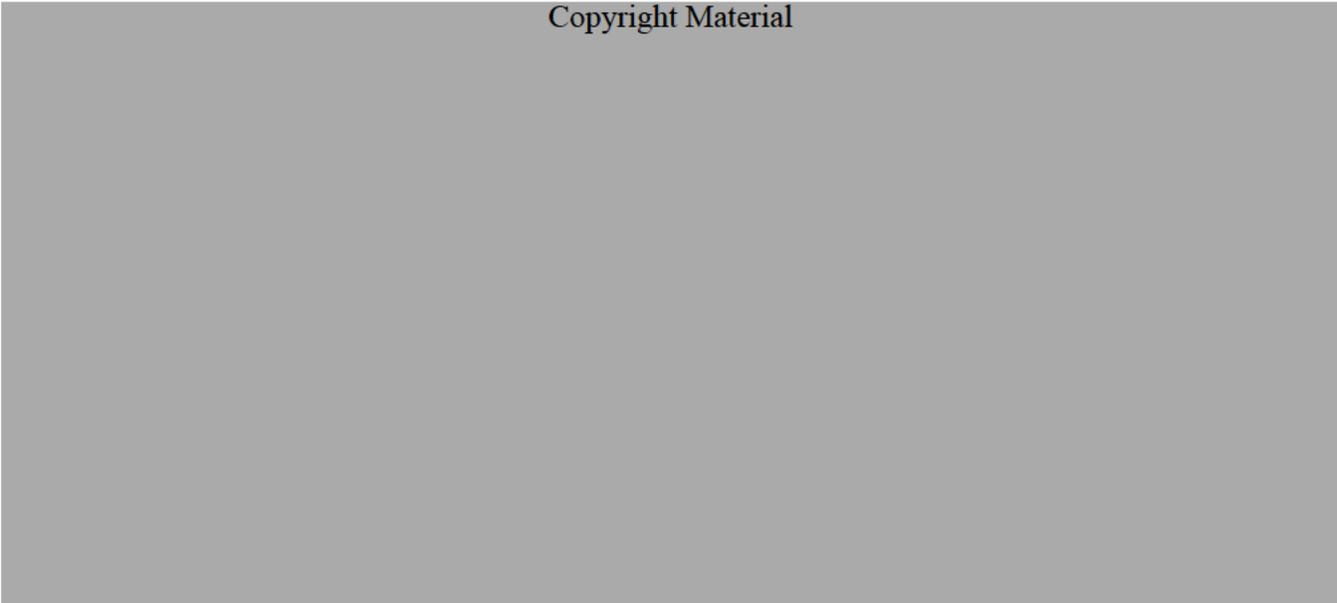


Figure 1. (A) Cumulative amount of K^+ (mEq) excreted by treatment in 24 hours and (B) Excretion rate of K^+ (mEq/h) by treatment on Day 4 after subtraction of excretion rate of control group. (Source: Table 1, Melikian et al. 1988)

The authors concluded that:

- The KCl solution showed greater urinary excretion of K^+ for 0-2 hour post dose. Urinary excretion during the 8-12 hour urine collection period was numerically lower when compared to that from suspension or capsule formulations.
- The extent of absorption of KCl from the three formulations was comparable for the 24 hour period.

2. Publication by Skoutakis *et al.*²

Skoutakis *et al* published a three-way cross-over study in 24 healthy male subjects, placed on a diet that restricted potassium intake to 65 ± 5 mEq/day. Single 40 mEq doses of KCl as wax-matrix tablets (6.7 mEq/tablet and 10 mEq/tablet) and as 20 % solution (40 mEq/15 mL) were used in the study. The absorption and total urinary excretion of K^+ after administration of 40 mEq dose of all three formulations were equal to approximately 90 % of the administered dose. The authors reported that, based on the area under the serum concentration versus time curve,

² Skoutakis VA *et al.*, Liquid and solid potassium chloride: Bioavailability and safety. *Pharmacotherapy*. 1984, 4: 392-397

the liquid and the two solid dosage forms were bioequivalent. Peak serum levels of K^+ were reported to occur at approximately 4 hours after administration of the slow-release formulations and at 1.5 hours with the liquid preparation. The maximum urinary excretion of K^+ occurred during the 4-6 hour collection period with the tablets and during the 2-4 hour collection period with the liquid supplement.

Further, the authors summarized information comparing different dosage forms from several studies and concluded that:

- The rates of K^+ absorption and excretion for the liquid and slow-release forms differ initially but the bioavailability is same in general.
- With regards to safety, lesions of the upper gastrointestinal tract appeared more frequently in association with the solid than with the liquid dosage forms. However, the gastrointestinal disturbances were more frequently reported with the liquid formulation.

3. Correspondence by Levene DL³

Levene DL wrote as a correspondence to the editor about a single dose study (24 mEq KCl as liquid or enteric coated tablets) in subjects on a normal diet with potassium intake of 80 mEq/day. Ten subjects received KCl solution, 12 were given dissolved effervescent tablets (this was a liquid formulation when administered) and 13 were given enteric coated tablets.

The urinary excretion of K^+ for the three formulations during the collection intervals is shown in Figure 2 below.

³ Levene DL. The absorption of potassium chloride – liquid vs. tablet. *CMA Journal*, 1973, 108: 1480-1481

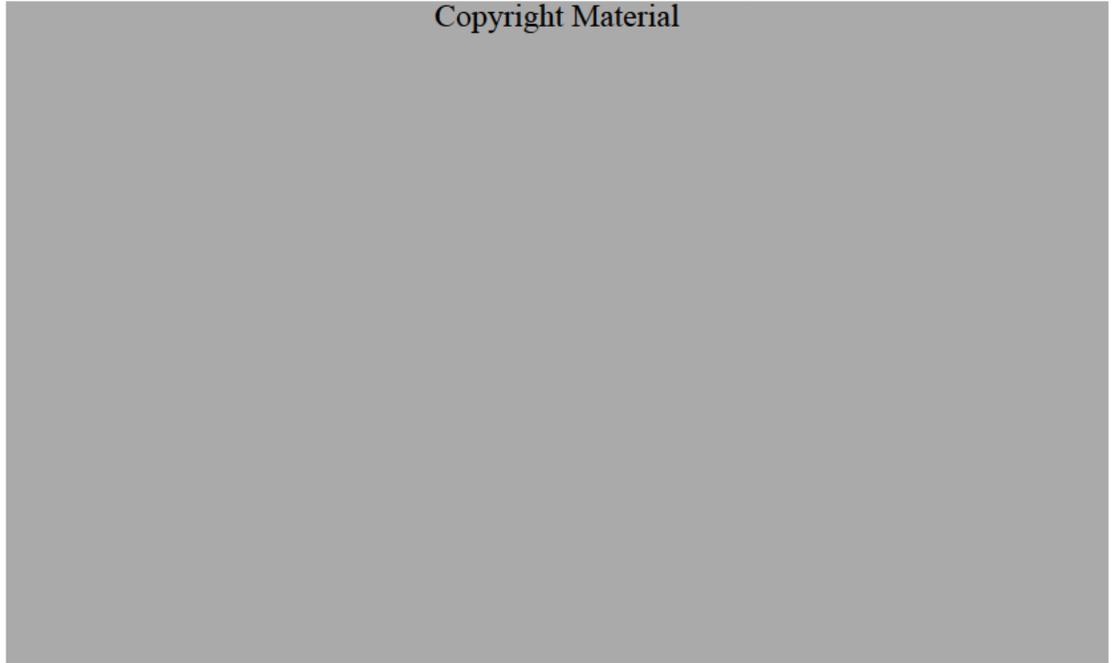


Figure 2. Mean urinary potassium excretion from liquid formulations (-▲-dissolved effervescent tablets and -□- solution) and -●- extended release tablets during first 6 hours after dose administration. (Source: Devene DL Correspondence to the Editor, 1973)

The conclusions from this correspondence were:

- Based on the excretion rates, K^+ was absorbed rapidly in the first few hours from the liquid formulations.
- The peak excretion of K^+ was achieved by 2-3 hours irrespective of the formulation.
- The study did not inform about the late absorption (after 6 hours post dose) of K^+ .

4. Publication by Lowance DC *et al.* ⁴

Lowance DC *et al.* compared the rate and extent of potassium absorption from a slow release tablet and a 10 % KCl solution in 12 healthy male subjects using a single 48 mEq dose in a two-way cross-over design. A control period of 4-7 days established the baseline for the electrolytes. A re-equilibration period of 4-7 days was implemented as washout between treatment periods. During the study, all subjects were maintained on a controlled, normal potassium diet under strict conditions in a metabolic research ward. On the drug-free days the diet included 50.4

⁴ Lowance DC *et al.* Bioequivalence of a slow release potassium tablet and a liquid potassium supplement. *International Journal of Clinical Pharmacology, Therapy and Toxicology.* 1982, 20: 204-208

mEq of K^+ . On the drug administration days, the dietary intake of potassium was 18 mEq in an evening meal. The calculated amount of K^+ remaining to be excreted after dose administration is shown in Figure 3.

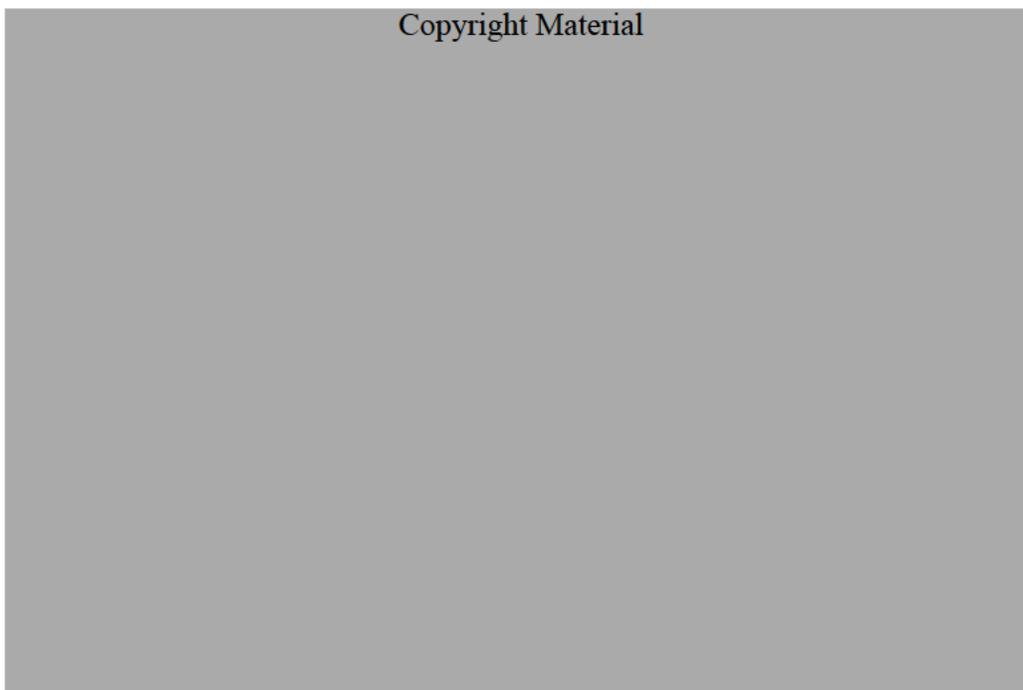


Figure 3. Percentage of potassium remaining to be excreted at times after administration of the potassium supplement. Mean values \pm SD are plotted. (Source: Lowance DC *et al.* 1982)

The notable observations from this publication are:

- The baseline excretion rate of K^+ was comparable for the two treatment arms prior to the administration of potassium supplements.
- Urinary potassium levels for first three hours with KCl solution were significantly greater than those seen after the slow release tablet.
- The estimated rate of K^+ excretion (by *Wagner* method) from the slow release tablet was about 30 minutes slower than that from the KCl solution. But K^+ was completely absorbed from both formulations within 24 hours.
- Gastrointestinal tolerance was generally good with both preparations. The incidence of adverse events reported to attending physicians (abdominal pain, nausea, heart burn and diarrhea) was slightly higher with KCl solution. Neither formulation was associated with evidence of gross or occult gastrointestinal bleeding.
- Majority of subjects (92 %) receiving KCl solution reported a bad taste or after taste.

5. Publication by Caplain H *et al.*⁵

The authors reported a single-blind, placebo controlled, single dose, cross-over study in 24 healthy subjects comparing microencapsulated KCl tablets (64 mEq) with KCl solution (67.5 mEq) and wax-matrix tablets (67.5 mEq). The washout between treatments was one week. Meals of identical composition were administered on each day. The diet contained an average of 75 mEq potassium. The Table 2 and Figure 4 below show the results of the study.

Table 2. Comparison of K⁺ excretion between liquid and solid formulations

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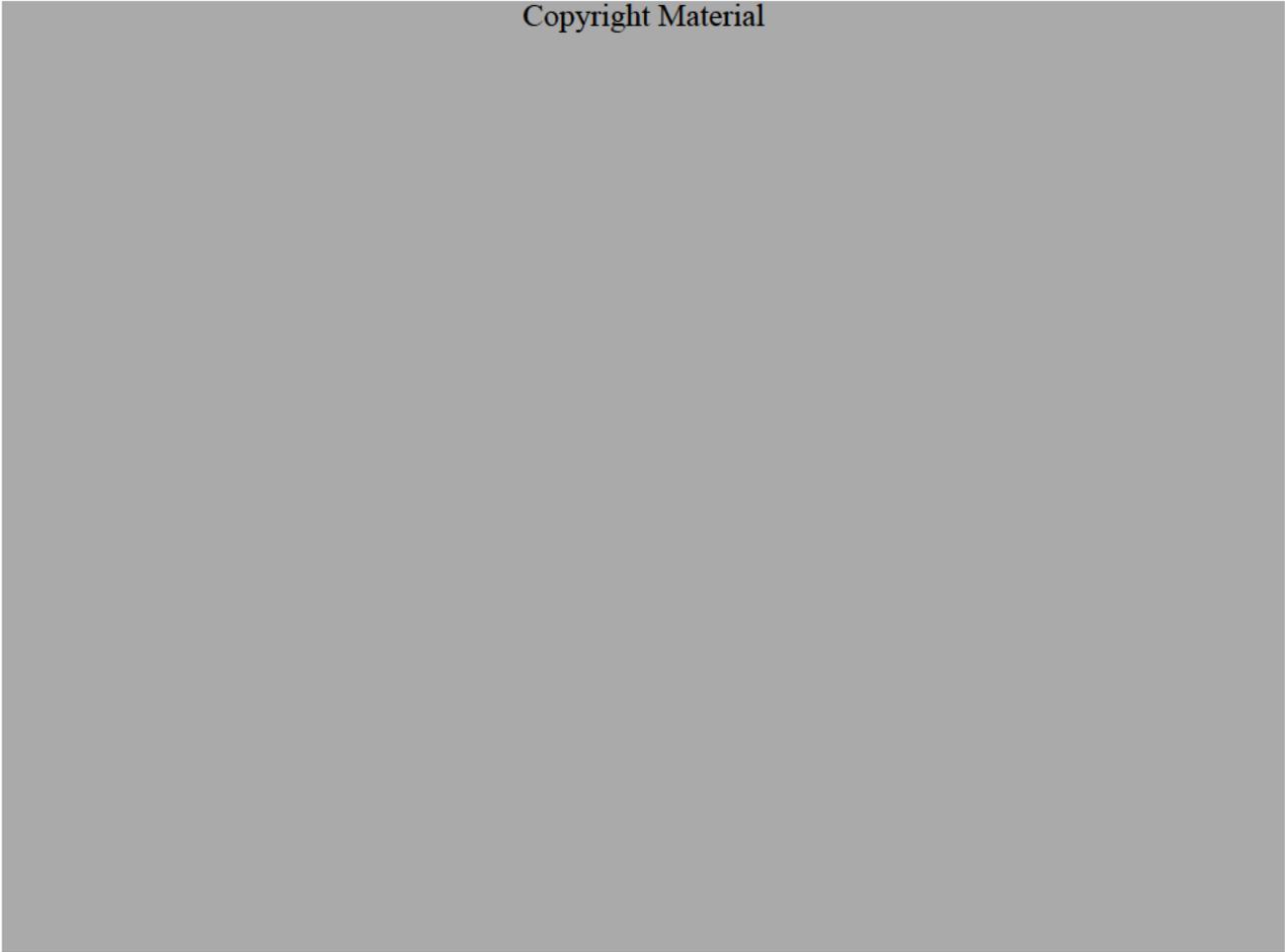


Figure 4. Cumulative excretion of potassium over 24 hours after administration of different KCl formulations

(Source for Table 2 and Figure 4: Caplain H *et al.*, 1991)

⁵ Caplain H *et al.* A single blind normal volunteer bioavailability study of a new microencapsulated potassium chloride tablet compared with two reference potassium formulations. *European Journal of Drug Metabolism and Pharmacokinetics*. 1991, 16: 241-244

Highlights from this study are:

- The cumulative amount of K⁺ excretion in urine, collected over a period of 12 hours was similar among all formulations but the kinetics of excretion varied from one formulation to the other.
- Liquid formulation showed higher urinary excretion for the first few hours compared to solid formulations as reported in other studies.

6. NDA 019123 (Klor-Con[®]) Approval Package from Drugs@FDA⁶

A four-way, planned sequence, cross-over study in 24 healthy subjects, comparing the bioavailability of Klor-Con[®] 8 mEq extended release (ER) tablet, Klor-Con[®] 10 mEq ER tablet, Slow-K[®] ER tablet and 10 % KCl solution. Bioavailability was assessed by urinary K⁺ excretion over 72 hour after administration of each of the four test products. After adjusting for the contribution of dietary potassium to total potassium excretion, there were no significant differences between any of the four products for urinary K⁺ excretion during the 24 hour collection period (Table 3). Urinary excretion from the KCl solution was higher for 0-6 hour collection period compared to other formulations.

Table 3. Baseline corrected mean cumulative urinary excretion of potassium

Formulation	Mean 0-24 hour K excreted in urine (SEM)
Klor-Con [®] 8 mEq ER Tablet	21.71 (2.06)
Klor-Con [®] 10 mEq ER Tablet	24.82 (2.15)
Slow-K [®] ER Tablet	21.87 (2.08)
10 % Kcl Solution	23.05 (2.05)

(Source: NDA 019123 (Klor-Con[®]) Approval Package from Drugs@FDA)

REVIEWER'S COMMENTS:

The results from the studies described above show that the bioavailability of KCl, as measured by the cumulative urinary excretion of K⁺ over a 24 hour post dose period, is comparable across the liquid formulation and various types of modified release products. As expected, the KCl oral solution showed higher initial urinary excretion during the 0-6 hour period, reflecting rapid absorption, relative to the slow release products. Conversely, the slow release products such as microencapsulated tablets or wax-matrix tablets showed slightly higher urinary excretion of potassium during the later collection periods. Further, for the approval of Klor-Con[®] ER Tablets⁶,

⁶ NDA 019123 Klor-Con[®] Approval Package from Drugs@FDA:
http://www.accessdata.fda.gov/drugsatfda_docs/NDA/pre96/019123_s000.pdf

a solution formulation was used as a reference in the bioequivalence study. The difference in the initial rate of absorption between the products was clearly evident. Despite this difference, the ER formulation was considered to be effective as it demonstrated K⁺ bioavailability. This suggests that the potential differences in rate of absorption of KCl from the solution formulation and modified release products may not be clinically relevant for K⁺ supplementation.

Although lesions of the upper gastrointestinal tract appeared more frequently in association with solid than with liquid formulations, other gastrointestinal disturbances (not associated with gross or occult gastrointestinal bleeding) were reported to be more frequent with the liquid form. In general the overall gastrointestinal tolerance to KCl can be considered to be at least similar for liquid and modified release products in these studies.

RECOMMENDATION:

From a clinical pharmacology perspective the proposed oral solution of KCl can be approved for use as a potassium supplement.

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