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8774 '01 SEP 10 P2:32

September 7, 2001

Via Federal Express
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 10-61
Rockville, MD 20857

Re: Docket No. 00P-1550, Citizen Petition Relating to Cefuroxime Axetil

Dear Sir or Madam:

On September 29, 2000, we submitted a Citizen Petition on behalf of GlaxoWellcome Inc., now GlaxoSmithKline (hereinafter "GSK"). That Petition asked, *inter alia*, that the Food and Drug Administration ("FDA") not approve any abbreviated new drug application ("ANDA") or application filed under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") for any cefuroxime axetil product that – unlike the innovator product Ceftin® Tablets – includes crystalline cefuroxime axetil.

In light of a recent USP decision that highlights the important differences between crystalline and amorphous forms of cefuroxime axetil, we renew our request. To reject GSK's position would to require adoption of an arbitrary interpretation of the FFDCA, one not supported by either a neutral principle of law or existing case law. In this supplemental filing, we ask that FDA instead adopt a rational interpretation consistent with applicable judicial precedent.

Background – USP confirms that crystalline cefuroxime axetil is different from amorphous cefuroxime axetil

The original GSK Citizen Petition pointed out that the then current United States Pharmacopeia ("USP") monograph for cefuroxime axetil excluded the crystalline form of the drug substance. Subsequently, as a result of an appeal of an initial decision to expand the USP drug substance monograph to include crystalline forms, the USP's Executive Committee and Board of Trustees issued a decision that effectively endorsed the proposition that amorphous cefuroxime axetil and crystalline cefuroxime axetil are materially different. (The USP's Revision Bulletin announcing the decision, and accompanying explanation of the impact on the text of the current USP cefuroxime axetil drug substance and cefuroxime axetil tablet monographs, is attached as Exhibit T.) We

00P-1550 SUP 4

submit that the USP's decision confirms the impropriety of treating amorphous cefuroxime axetil and crystalline cefuroxime axetil as the "same" for purposes of the FFDCA.

Specifically, the USP reached two conclusions in addressing the appeal. First, consistent with the initial USP decision, it approved a change in the drug substance monograph, requested by an ANDA applicant, that recognizes crystalline cefuroxime axetil as a USP substance. Of critical importance, however, the USP (and apparently the ANDA applicant as well) recognized that amorphous cefuroxime axetil and crystalline cefuroxime axetil are sufficiently different so that the drug substance must be labeled as either amorphous or crystalline. If amorphous cefuroxime axetil and crystalline cefuroxime axetil were the same, there would, of course, be no reason to distinguish between them.

Second, in response to considerable evidence that amorphous cefuroxime axetil and crystalline cefuroxime axetil have significantly different properties, as demonstrated by results in both *in vitro* and *in vivo* tests, the USP determined that the product monograph for cefuroxime axetil tablets should be amended to require that the product be labeled to indicate whether the tablets contain amorphous cefuroxime axetil or crystalline cefuroxime axetil and, if they contain a mixture of the two ingredients, the percentages of each. Again, and of critical importance, if amorphous cefuroxime axetil and crystalline cefuroxime axetil were the same, there would no justification for requiring that products be labeled to indicate which they contain and to state the percentages of the amorphous and crystalline ingredients in any mixture.[1]

The final USP decision simply reflects the undeniable reality that crystalline cefuroxime axetil differs in material ways – specifically in solubility and absorption – from amorphous cefuroxime axetil. Thus, it is highly unlikely that any product made

[1] As FDA is aware, the USP was also asked to consider further monograph provisions that would serve to assure consistency, from batch to batch and over the shelf-life of an individual batch, in the relative ratios of the different crystalline polymorphs of cefuroxime axetil and of the crystalline-to-amorphous forms. The USP apparently deferred to FDA on those issues. Along similar lines, GSK renews its request to FDA, made in the original Citizen Petition, that any ANDA applicant that receives approval (over GSK's legal objections) for a product containing crystalline cefuroxime axetil be required to establish and adhere to appropriate specifications (supported by validated analytical methods) for solid-state form.

solely from crystalline cefuroxime axetil would test bioequivalent to a product made solely from amorphous cefuroxime axetil. It is only when the different ingredients are mixed, in a mixture containing a relatively small amount of crystalline material, that bioequivalence to the amorphous form within the range accepted by FDA can confidently be achieved.[2]

FDA approval of an ANDA for a product that contains a different active ingredient than the amorphous cefuroxime axetil found in Ceftin Tablets would violate the law in two respects: First, it would involve the approval of a generic product whose "active ingredient" is not the "same" as that of the innovator product, in violation of FFDCA Section 505(j)(2)(A)(ii)(I). Second, because the different forms must (to conform with the amended USP product monograph) be identified and quantified in the labeling, the generic product would not have the same labeling as the innovator such that approval as an ANDA would violate FFDCA Section 505(j)(2)(A)(v).

Different Active Ingredient

FDA has suggested, in the context of the USP hearing, that it believes that the term "same active ingredient" refers to the same salt or ester of the same active moiety but that "differences in physical form are not relevant to a determination of a same active ingredient." Memorandum from Gary Buehler to the Executive Committee of the Council of Experts, United States Pharmacopeia (July 10, 2001). This position conflicts with a key prior agency interpretation. In the preamble to its final regulations implementing the statutory provisions in question, FDA stated that it may in some cases prescribe additional standards to assure sameness, such as standards for crystalline structure. 57 Fed. Reg. 17,950, 17,959 (Apr. 28, 1992). That published preamble constitutes an advisory opinion pursuant to 21 C.F.R. 10.85(d)(1), which "represents the formal position of FDA on a matter and ... obligates the agency to follow it until it is amended or revoked." 21 C.F.R. 10.85(e). Thus, the FDA position, as articulated in the context of the USP proceeding, cannot be the agency's legal justification for any approval. Instead, in accordance with its prior interpretation, FDA must recognize that differences between crystalline and amorphous forms can be relevant, and FDA can

[2] This fact, which FDA certainly recognizes, is admitted in the Ranbaxy patent application submitted as Exhibit N to the Citizen Petition (supplemental submission of October 30, 2000): "Crystalline cefuroxime axetil ... does not exhibit adequate bioavailability upon oral administration." Id., p. 1, line 17.

ignore them only if, as is not the case here, there is no material difference between the different forms.

Moreover, even the position taken in the preamble grants FDA more latitude than the statute permits. Simply put, an agency position that it could ignore differences between crystalline and amorphous ingredients, where those differences undeniably affect the function of the ingredients, would be arbitrary and capricious.

An FDA conclusion that amorphous cefuroxime axetil and crystalline cefuroxime axetil, despite materially different bioavailability, must be considered to be the same would be unsupportable. As FDA plainly recognizes elsewhere, the issue of whether two products have the "same active ingredient" is not determined simply by the active moiety that will be produced in the bloodstream. Thus, FDA states unequivocally, in the context of ANDA approvals, that a "different ester or salt" is a "different active ingredient," see 21 C.F.R. 314.93(d)(3), even where, once in the bloodstream, those salts or esters would produce the same active moiety. That is true, even if it could be shown (as it might be shown in some circumstances) that a tablet containing one salt form of a drug would be bioequivalent to a tablet containing a different salt form (or an ester form) of that drug, in the sense that each would produce blood levels of the same active moiety at the same rate and to the same extent. Why then would FDA deem different salts and esters to be *never* the "same" and deem different crystalline and amorphous forms of a particular salt or ester to be *always* the "same"? GSK suggests, respectfully but forcefully, that there is no neutral, rational principle to support such a position.

There is, moreover, an alternative interpretation of the statute, developed and articulated by FDA and endorsed by the courts, that should be applied in these circumstances. In Serono Laboratories, Inc. v. Shalala, 158 F.3d 1313 (D.C. Cir. 1998), the Court of Appeals for the District of Columbia Circuit upheld an FDA decision that a generic version of an innovator product that differed in some respects from the innovator could be considered the same because, in addition to exhibiting "clinical equivalence to the pioneer," the generic showed "chemical identity to the extent possible." 158 F.3d at 1321. Chemical structure was a primary focus in Serono, but the concept of identity to the extent possible logically applies as well to identity in solid-state form, given the potentially different properties of different physical forms. In Serono, the question of what constituted identity to the extent possible was, to the court's satisfaction, illustrated by FDA's finding that the innovator itself, batch-to-batch, had variations wide enough to encompass the variation admitted to exist between the generic and the innovator ("limitations on inherent isoform variation to the same extent as in the pioneer" in the

context of that product). Id. This interpretation was found by the court to be reasonable and permissible. Id.

Applied to the present situation, that interpretation would not permit FDA to conclude that crystalline cefuroxime axetil and amorphous cefuroxime axetil, considered different enough by USP to warrant differentiation in labeling, are in fact "identical" within the meaning of 21 C.F.R. 314.92(a)(1) or the "same" within the meaning of FFDCA § 505(j)(2)(A)(ii)(I). There is no dispute that it is possible to make amorphous cefuroxime axetil. Thus a product that is not totally amorphous does not exhibit identity "to the extent possible." Nor is there any possible argument that a variation that includes crystalline material includes "limitations to the same extent" as those applicable to the innovator. GSK does not permit any crystalline cefuroxime axetil in its product.

An ANDA containing both amorphous cefuroxime axetil and crystalline cefuroxime axetil is simply a combination product, combining two different active ingredients, as its label will, consistent with the USP's decision, disclose. It is no answer to say that the combination of a small amount of less bioavailable crystalline drug substance with amorphous drug substance produces a mixture whose bioavailability is close enough to that of the amorphous Ceftin Tablets to fall within the range permitted by FDA. It might well be true that if one were to mix, for example, 10 or 15 percent cefuroxime sodium (a salt of cefuroxime of negligible oral bioavailability) with amorphous cefuroxime axetil (an ester of significantly greater bioavailability), the resulting mixture would be bioequivalent to Ceftin Tablets, within the range permitted by FDA.

Under FDA's interpretation of the statute, however, cefuroxime sodium is not the same active ingredient as cefuroxime axetil. There is simply no scientific neutral principle that permits FDA to maintain that different salts or esters are *never* the same active ingredient while different crystalline and amorphous forms, *even if* those forms exhibit clearly different physical and pharmacokinetic properties, are *always* the same active ingredient. Such an arbitrary position is, of course, not permitted by the Administrative Procedure Act or by the FFDCA.

Labeling

It is black letter law that the ANDA product must have the same labeling as the innovator, FFDCA § 505(j)(2)(A)(v). The only differences permitted by FDA regulations relate to "expiration date, formulation, bioavailability, or pharmacokinetics,

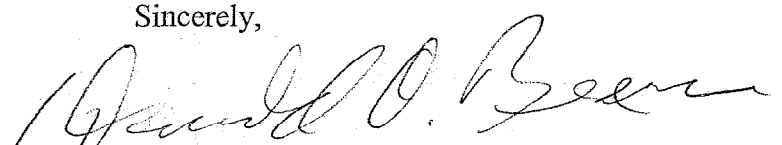
labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity." 21 C.F.R. 314.94(a)(8)(iv).

To conform to the USP drug product monograph, as amended effective September 30, 2001, a generic product that is not 100 percent amorphous will have to be labeled differently from Ceftin Tablets, which are correctly labeled as being "in the amorphous form." That difference in labeling does not result from a difference in formulation. Instead, it results from a difference in the active ingredients of the products, as discussed above.[3]

Conclusion

For the reasons discussed above, and those set out in the original GSK Citizen Petition and previous supplemental filings, approval of a generic version of Ceftin Tablets that contains a different active ingredient, i.e., one that contains crystalline drug substance as opposed to strictly amorphous drug substance, would be unlawful. The simple expedient of calling such a product the same when it is not the same will be legally unsustainable. We ask, accordingly, that FDA conclude that it cannot approve a generic product whose active ingredient does not show "identity to the extent possible" to the active ingredient of the innovator product.

Sincerely,



Donald O. Beers
David E. Korn

[3] If, on the other hand, FDA does not require a generic product to be labeled in accordance with the USP monograph, then the generic product would not comply with the USP monograph and cannot be considered the same as Ceftin Tablets on that basis.

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U.S. Pharmacopeia
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BULLETIN ANNOUNCING REVISION
TO USP 24 AND TO NF 19

By authority of the United States Pharmacopeial Convention, Inc.
Prepared by the Council of Experts and published by the Board of Trustees

Mary Ann Koda Kimble, Chair
USP Board of Trustees
Council of Experts

Roger L. Williams, Executive Vice President, and Chairman, USP

Official September 30, 2001

Released August 14, 2001

(Continued)

All inquiries and comments regarding *USP 24* text and *NF 19* text should be addressed to the Executive Secretariat, USP-NF, 12601 Twinbrook Parkway, Rockville, MD 20852

12601 Twinbrook Parkway
Rockville, MD 20852

301-881-0666

www.usp.org

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REVISION BULLETIN

On May 25, 2001, an appeal was filed on revisions made to the Cefuroxime Axetil Monograph. These revisions were scheduled to become official on August 1, 2001. To allow sufficient opportunity to decide on the appeal, the Executive Committee to the Council of Experts postponed the official date of the revision to September 30, 2001.

On August 6, 2001, the Executive Committee met and upheld the decision of the Expert Committee thereby approving the revisions to the Cefuroxime Axetil monograph, which recognizes the crystalline and amorphous forms of the substance. The Executive Committee then approved a subsequent modification to the Cefuroxime Axetil Tablet monograph to require a labeling statement providing information on the percentage of crystalline and/or amorphous forms in the dosage form.

The Board of Trustees has upheld the Executive Committee's decision on the Cefuroxime Axetil monograph and has approved the release date of this Bulletin. Changes to the monographs are official on September 30, 2001.

12601 Twinbrook Parkway
Rockville, MD 20852

301-881-0666
www.usp.org

Revision Recommended by PA7

Following Hearing of 7/30/01

Mgh# 14152

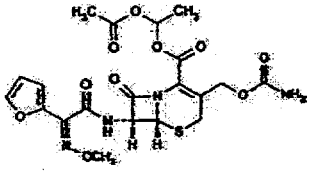
1.

Cefuroxime Axetil, *USP 24* page 355 and page 2804 of the *Second Supplement.*

Cefuroxime Axetil (continued) 2.

2C08820 (PA7)

Cefuroxime Axetil



$C_{20}H_{22}N_4O_{10}S$ 510.48

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-, 1-(acetyloxy)ethyl ester, [6*R*-[6α,7β(*Z*)]]-.

(*RS*)-1-Hydroxyethyl (6*R*,7*R*)-7-[2-(2-furyl)glyoxylamido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 7-(*Z*)-(*O*-methyloxime), 1-acetate 3-carbamate [64544-07-6].

» Cefuroxime Axetil is a mixture of the ~~amorphous~~ diastereoisomers of cefuroxime axetil ($C_{20}H_{22}N_4O_{10}S$). It contains the equivalent of not less than 745 µg and not more than 875 µg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mg, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards (11)—*USP Cefuroxime Axetil RS*—*USP Cefuroxime Axetil Delta-3 Isomers RS.*

Identification, *Infrared Absorption* (197K).

Crystallinity (695)—~~The particles do not show birefringence or extinction positions. It is amorphous.~~

Water, *Method I* (921): not more than 1.5%.

Diastereoisomer ratio—

0.2 M Monobasic ammonium phosphate, Mobile phase, Internal standard solution, Resolution solution, Standard preparation, Assay preparation, and *Chromatographic system*—Prepare as directed in the *Assay.*

Procedure—Proceed as directed for *Procedure* in the *Assay.* Calculate the ratio of cefuroxime axetil diastereoisomer A to the sum of the cefuroxime axetil diastereoisomers A and B taken by the formula:

$$r_A/(r_A + r_B),$$

in which r_A and r_B are the peak responses of the cefuroxime axetil diastereoisomers A and B, respectively: between 0.48 and 0.55 is obtained.

Change to read:

Add the following:

Labeling—Label it to indicate whether it is amorphous or crystalline.

Change to read:

Particles that do not show birefringence or exhibit extinction positions are amorphous, and particles that show birefringence and exhibit extinction positions are crystalline.

Continued.....

Assay—

0.2 M Monobasic ammonium phosphate—Dissolve 23.0 g of monobasic ammonium phosphate in water to obtain 1000 mL of solution.

Mobile phase—Prepare a suitable filtered and degassed mixture of *0.2 M Monobasic ammonium phosphate* and methanol (620:380). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of acetanilide in methanol containing 5.4 mg per mL.

Resolution solution—In a 50-mL volumetric flask, mix 10.0 mL of a solution of USP Cefuroxime Axetil RS in methanol containing 1.2 mg per mL, 5.0 mL of *Internal standard solution*, and 3.8 mL of a solution of USP Cefuroxime Axetil Delta-3 Isomers RS in methanol containing 0.16 mg per mL. Dilute with *0.2 M Monobasic ammonium phosphate* to volume, and mix.

Standard preparation—Transfer about 30 mg of USP Cefuroxime Axetil RS, accurately weighed, to a 25-mL volumetric flask, dissolve in methanol, dilute with methanol to volume, and mix. Promptly transfer 10.0 mL of this solution to a 50-mL volumetric flask, add 5.0 mL of *Internal standard solution* and 3.8 mL of methanol, dilute with *0.2 M Monobasic ammonium phosphate* to volume, and mix. [NOTE—Use this *Standard preparation* promptly, or refrigerate and use on the day prepared.]

Assay preparation—Transfer about 30 mg of Cefuroxime Axetil to a 25-mL volumetric flask, dissolve in methanol, dilute with methanol to volume, and mix. Promptly transfer 10.0 mL of this solution to a 50-mL volumetric flask, add 5.0 mL of *Internal standard solution* and 3.8 mL of methanol, dilute with *0.2 M Monobasic ammonium phosphate* to volume, and mix. [NOTE—Use this *Assay preparation* promptly, or refrigerate and use on the day prepared.]

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 278-nm detector and a 4.6-mm × 25-cm column containing 5-µm packing L13. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.4 for acetanilide, 0.8 for cefuroxime axetil diastereoisomer B, 0.9 for cefuroxime axetil diastereoisomer A, and 1.0 for cefuroxime axetil delta-3 isomers; the resolution, R, between cefuroxime axetil diastereoisomer A and B is not less than 1.5; and the resolution, R, between cefuroxime axetil diastereoisomer A and cefuroxime axetil delta-3 isomers is not less than 1.5. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the column efficiency is not less than 3000 theoretical plates when measured using the cefuroxime axetil diastereoisomer A peak; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of cefuroxime ($C_{16}H_{16}N_4O_8S$) in each mg of Cefuroxime Axetil taken by the formula:

$$(W_S/W_U)(P_S/100)(100 - K)(R_U/R_S)$$

in which W_S is the weight, in mg, of USP Cefuroxime Axetil RS taken to prepare the *Standard preparation*; W_U is the weight, in mg, of Cefuroxime Axetil taken to prepare the *Assay preparation*; P_S is the designated cefuroxime ($C_{16}H_{16}N_4O_8S$) content, in µg per mg, of anhydrous USP Ceforoxime Axetil RS; K is the percentage water content of USP Cefuroxime Axetil RS; and R_U and R_S are the ratios of the sum of the peak responses of the cefuroxime axetil diastereoisomers A and B to the peak response of the internal standard obtained from the *Assay preparation* and the *Standard preparation*, respectively.

* * * * * * * * * * *

Revision Recommended by PA7

Following Hearing of 7/30/01

Mgh# 14154

1.

Cefuroxime Axetil Tablets, *USP 24* page 356 and page 3203 of the *Fourth Supplement*.

Cefuroxime Axetil Tablets (continued)

2.

2C08825 (PA7)

Cefuroxime Axetil Tablets

» Cefuroxime Axetil Tablets contain the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—*USP Cefuroxime Axetil RS. USP Cefuroxime Axetil Delta-3 Isomers RS.*

Identification—The chromatogram of the *Assay preparation* exhibits major peaks for cefuroxime axetil diastereoisomers A and B, the retention times of which correspond to those exhibited in the chromatogram of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.

Dissolution ⟨711⟩—

Medium: 0.07 N hydrochloric acid; 900 mL.

Apparatus 2: 55 rpm.

Times: 15 and 45 minutes.

Procedure—Determine the amount of cefuroxime ($C_{16}H_{16}N_4O_8S$) dissolved by employing UV absorption at the wavelength of maximum absorbance at about 278 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Cefuroxime Axetil RS, equivalent to about 0.01 to 0.02 mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mL, in the same *Medium*.

Tolerances—Not less than 60% (*Q*) of the labeled amount of $C_{16}H_{16}N_4O_8S$ is dissolved in 15 minutes, and not less than 75% (*Q*) is dissolved in 45 minutes■; except that where Tablets are labeled to contain the equivalent of 500 mg of cefuroxime, not less than 50% (*Q*) of the labeled amount of $C_{16}H_{16}N_4O_8S$ is dissolved in 15 minutes, and not less than 70% (*Q*) is dissolved in 45 minutes.■

Add the following:

Labeling—The labeling indicates whether the Tablets contain amorphous or crystalline Cefuroxime Axetil. If Tablets contain a mixture of amorphous and crystalline Cefuroxime Axetil, label to indicate the percentage of each contained therein.

Continued.....

Assay—

0.2 M Monobasic ammonium phosphate, Mobile phase, Internal standard solution, Resolution solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Cefuroxime Axetil.*

Assay preparation—Finely powder not fewer than 10 Tablets accurately counted. Transfer the powder, with the aid of methanol to a volumetric flask of such capacity that when filled to volume the solution will contain the equivalent of about 2 mg of cefuroxime ($C_{16}H_{16}N_4O_8S$) per mL. Add methanol to fill the volumetric flask to about half of its capacity, and shake by mechanical means for about 10 minutes. Dilute with methanol to volume, and mix. Filter a portion of this stock mixture, and transfer 5.0 mL of the filtrate to a 50-mL volumetric flask. Add 5.0 mL of *Internal standard solution* and 8.8 mL of methanol, dilute with *0.2 M Monobasic ammonium phosphate* to volume, and mix. NOTE—Use this *Assay preparation* promptly, or refrigerate and use on the day prepared.

Procedure—Proceed as directed in the *Assay* under *Cefuroxime Axetil.* Calculate the quantity, in mg, of cefuroxime ($C_{16}H_{16}N_4O_8S$) in each Tablet taken by the formula:

$$(V/1250N)(P_S W_S)(R_U / R_S),$$

in which V is the volume, in mL, of the volumetric flask used to prepare the stock mixture; N is the number of Tablets taken; and the other terms are as defined therein.

* * * * * * * * * * * *

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