## Osmolarity Values

Interest in the quality of drug products has continued to increase during the 5-year preparation of USP XIX. Several new discerning techniques of determining the identity, quality, purity, and strength have been included[1]. High-pressure liquid chromatographic methods, X-ray diffraction spectrometric methods, and atomic absorption spectrometric methods have been included as new pharmacopeial tests. Other strides in the new compendial requirements include particulate matter standards on large volume parenterals, pharmaceutical container standards, and expiration dates on drug products.

During the past revision period, the USP advisory panel on electrolytes and parenteral therapy unanimously recommended that the osmolarity value be included in the labeling for parenteral electrolytes and large volume parenterals which are commonly given intravenously. The objective of this recommendation was to alert physicians to the fact that they may be injecting solutions that are markedly hypotonic or hypertonic[2].

A brief survey of USP XIX indicates that for several preparations the osmolarity value must be stated on the label in milliosmoles per liter. Furthermore, different sizes and concentrations of these preparations are commercially available.

An array of concentration ranges of different parenteral preparations are official in USP XIX—*viz.*, calcium chloride (2–10%), calcium gluconate (1%), calcium levulinate (10%), dextrose (2.5–50%), dextrose and sodium chloride (2.5–25% and 0.11–0.9%, respectively), Ringers injection (0.85% sodium chloride, 0.3% potassium chloride, and 0.33% calcium chloride), magnesium sulfate (10–50%), mannitol (5–25%), mannitol and sodium chloride (5–15% and 0.45%, respectively), potassium chloride (8–24%), sodium bicarbonate (1.4–8.4%), sodium chloride (0.9%), and sodium lactate (0.19–5.6%). In view of the multitude of commercially available preparations, ranging from very dilute to saturated and/or supersaturated concentrations, the label requirement of the osmolarity value will become somewhat confused. Not only are these relative values of different preparations impractical to measure in concentrated solutions using a conventional osmometer, but they also markedly deviate from the expected values. In principle, the osmotic relationships can be considered in relation to other colligative properties and are indeed valid only for dilute solutions.

Additionally, our experience has demonstrated that some concentrated solutions are out of the measurable limits, some do not freeze, and some show deviations from calculated values when subjected to the normal operating conditions of the osmometer.

In view of the apparent controversy and confusion, additional guidelines are warranted if the manufacturer is to serve the community in a meaningful manner and the desired objectives are to be achieved. Unfortunately, the USP did not indicate any statement(s) in regard to this requirement. It is hoped that more uniform labeling can be developed for transmitting important information to various health-care professionals. Finally, it is surprising that this problem failed to attract our attention in the comment-proof stage of USP XIX.

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[1] "The United States Pharmacopeia," 19th rev., Mack Publishing Co., Easton, Pa., 1975 and its 1st supplement.
[2] Dr. Daniel Banes, United States Pharmacopeia, Rockville, Md., personal communication.

## Propylene Glycol USP—Harmful or Fatal If Swallowed!

A major supplier[1] of propylene glycol clearly indicates on the container label that the product is of USP quality. On the same label in red letters, half the size of the name of the product, is the word "CAUTION!" followed by the statements "Harmful or fatal if swallowed. Do not take internally." I am aware that propylene glycol is used as a solvent for vitamins taken orally as well as for other products administered by the oral route. A paper by Zaroslinski *et al.*[2] refers to propylene glycol having a relatively low order of toxicity and possessing pharmacological inertness. I know of at least one major hospital pharmacy that uses propylene glycol as a solvent for certain oral medications.

I do not understand how a well-known purveyor of a product which purports to meet the specifications of the USP can be allowed to include false, misleading, and patently incorrect information on a container label.

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[1] Sargent-Welch Scientific Co., Skokie, IL 60076
[2] J. F. Zaroslinski, R. K. Browne, and L. H. Possley, *Toxicol. Appl. Pharmacol.*, **19**, 573(1971).