LETTERS TO THE EDITOR

GLASS PARTICLES IN THE SOLUTION OF OPENED GLASS AMPULES

To the Editor: Many nuclear medicine procedures require the utilization of pharmaceuticals that are supplied in glass ampules. Examples are intravenous Persantine (DuPont Pharma, Billerica, MA) and furosemide. Although it has been reported that glass particles are commonly found in injectable pharmaceuticals taken from glass ampules (*1–4*) and that the injection of such macroparticulate components can be hazardous (*5–6*), many physicians, technologists and nurses routinely inject these intravenous pharmaceuticals without first filtering them through a micropore or in-line filter.

At our clinic we microscopically evaluated the residual material remaining on the syringe side of a 5-micron filter needle for glass particles. Of the 12 samples we evaluated, glass particle contamination could be seen in all samples. The mean number of observed particles was 30 with particle size ranging from 5–130 microns.

Although the number and size of particles infused for an individual patient receiving a single ampule injection may have negligible physiological effect, chronic exposure to these particles is likely to be harmful. Therefore, we recommend that when pharmaceuticals are available in either a rubber-stopped vial or glass ampule, the former should be chosen unless the pharmaceutical is first passed through a filter needle. At present, both furosemide and the larger 50-mg ampule of intravenous Persantine are offered in rubber-stopped vials.

If pharmaceuticals supplied in glass ampules are used, however, the bolus method should not be used when either aspirating or injecting the pharmaceuticals through a filter needle. Sabon et al. (*3*) have theorized that high pressure allows glass particles to penetrate the filter, thereby negating the purpose of the filter.

We further recommend that individuals involved in the preparation and/or injection of pharmaceuticals supplied in glass ampules should be reminded of the potential hazards. Due to the variability of institutional protocols for the handling of these products, professionals to be alerted are pharmacists, technologists, physicians and nurses.

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THE PACKAGING OF LIGHT-SENSITIVE COLD KITS

To the Editor: I appreciate Dr. Chilton's recent remarks and correction (*1*) regarding my previous Letter to the Editor (*2*), in which I did not list Hepatolite® as one of the cold kits susceptible to photolytic degradation.

In his letter, Dr. Chilton mentioned that both the 1994 USP DI® *Drug Information for the Health Care Professional* (*3*) and the *United States Pharmacopeia 22* and *National Formulary 17* (*USP 22/NF 17*) (*4*) failed to insert the cautionary note concerning the light sensitivity of ^{99m}Tc-disofenin (*1*). It appears that the monographs for ^{99m}Tc-disofenin in both the new 1995 USP DI (*5*) and the newly revised *USP 23/NF 18* (*6*) still fail to state any light sensitivity cautionary statement for ^{99m}Tc-disofenin. In addition the official monograph for ^{99m}Tc-albumin colloid in *USP 23/NF 18* (*9*) fails to mention the light sensitivity, although the package insert for the Microlite® kit for the preparation of ^{99m}Tc-albumin colloid (*7*) and the monograph for ^{99m}Tc-albumin colloid listed in the 1995 USP DI (*8*) do include cautionary statements regarding light sensitivity for ^{99m}Tc-albumin colloid.

The US Food and Drug Administration (FDA) recently approved the Neurolite® cold kit for the preparation of ^{99m}Tc-bicisate to be used for the localization of stroke (*10*). The Neurolite cold kit consists of two nonradioactive vials, A and B. The contents of vial A are light sensitive (*10*). Table 1 lists those light-sensitive cold kits that have been approved by the FDA for the preparation of ^{99m}Tc- and ^{111}In-labeled radiopharmaceuticals.

It is common practice for cold kit manufacturers to package light-sensitive drugs or drug components in clear and colorless glass vials or syringes (Table 1). Although this is contrary to the standard practice of protecting light-sensitive drugs in light-resistant containers (e.g., amber vials), a clear and colorless container has several advantages over the light-resistant colored container. It is less expensive to manufacture (i.e., ~25% cheaper), it is exempted from meeting the light transmission testing requirement as stated in *USP 23/NF 18* (*11*), and it enables visual inspection of the drug products to examine color change, clouding appearance or precipitate formation.

According to *USP 23/NF 18*, a clear and colorless or a translucent container may be made light resistant by covering it with an opaque substance such as a light-resistant carton or box (*12*). In this case, the label on both the immediate container (e.g., glass vial or syringe) and on the outer container (e.g., light-resistant carton or box) must bear a statement that the opaque covering (e.g., light-resistant carton or box) is needed until the contents are to be used or administered (*12*). "Protect from light" is the most commonly used warning statement for the labeling of a light-sensitive drug or drug component.

Most of the light-sensitive cold kits listed in Table 1 do comply with the *USP 23/NF 18* requirement that the labels on both the immediate and outer containers must state "protect from light." However, there are two light-sensitive cold kits that fail to