

8566 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

of bacterial contamination and a requirement that there be no pseudomonas. The USP and NF are now moving toward limiting the level of contamination in ophthalmic ointments, but there are still no other Government or industry standards for melting range and particle size even though contaminated ointment or ointment containing large crystals can cause additional damage to the eyes being treated.

Even though discoloration of pharmaceuticals generally is the initial sign of instability and degradation, neither the FDA nor the compendia are formally concerned with this problem so long as the products comply with the USP or NF. The military considers it essential that products retain their effectiveness until the time of use and accordingly DPSC has, for over ten years, included color standards in specifications for injections.

DPSC specifications for certain drug products require individual tablet assays of the product. The USP and NF are now requiring individual tablet assays to an increasing extent. DPSC also included requirements for dissolution rate of tablets and capsules long before this requirement was considered by the USP and NF. Currently, a concentrated effort is being made in pharmaceutical investigations to correlate the dissolution rate with bio-availability.

An important factor of military specifications are the requirements for accelerated aging tests and packaging and packing to ensure stability until the time the products are used.

The Medical Directorate of DPSC is a major contributor to the USP and NF in establishing standards for the country and has a member on the USP/NF Panel on Therapeutic Equivalency. Following are examples of