

Bio-availability involves the release of medication from a dosage form that can be absorbed within the patient and assert its therapeutic intent. A growing list of drugs is being reported in medical literature which reveals that the same drug manufactured by different companies using different formulations and manufacturing and quality control conditions can yield a product that meets all current requirements, but does not give the anticipated bio-availability characteristics, such as blood levels and urine concentration. These products include tetracycline tablets, Sodium Heparin Injection, Sodium Warfarin tablets, Sodium Diphenyl Hydantoin Capsules, "Tedral" type tablets and Oxytetracycline Tablets.

On this subject, Dr. Edwards, Commissioner of the Food and Drug Administration, has stated that:

"It has become increasingly apparent that drug products which purport to be equivalent and which may satisfy chemical and other analytical tests of equivalence, may not be therapeutically equivalent. We believe the key to the problem lies in what we refer to as bio-availability. We have found that comparable bio-availability frequently does not exist for products that are otherwise, so far as concurrently available methods are concerned, identical. We are not fully aware of the extent of this problem, but know that it exists particularly in tablet or capsule dosage forms. Among other factors, solubility of the drug substance, the amount of active drug in the dosage form, the excipients used, and certain aspects of the manufacturing processes play a role."

To ensure that such products will give suitable therapeutic responses, rather than merely comply with applicable laboratory tests, DPSC adds bio-availability standards to its specifications to assure that the drug products will yield the desired therapeutic effect.

Military specifications for ophthalmic ointments for over ten years have included standards for melting range, particle size, and limits