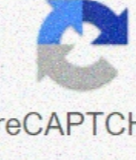


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In Vitro Release Testing of Semi-Solid Dosage Forms

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BACKGROUND

In vitro release testing (IVRT) is used to monitor the release and diffusion of drug products from semisolid dosage forms (1-12) and has long been considered a valuable tool in formulation development. IVRT has also been used to screen formulations to select promising candidates, (12-16) and, importantly, accepted for use to obtain a waiver of bioequivalence studies following postapproval changes to a product (17). A comprehensive review relating to the methodology, application, and equipment used in IVRT and published results using this technique is provided in this paper.

In vitro diffusion studies were used by Tehrani et al. (12) to investigate the influence of various additives on the release of procainamide from different topical vehicles, and they observed that the release was considerably higher in formulations containing 2-propanol caused by decreasing the viscosity of the formulation which proved to be helpful in screening the formulations for relative availability of the drug. The application of IVRT has many additional benefits such as its use in product development (18), identification of critical manufacturing variables, giving in vivo performance, and product performance assessment including batch-to-batch and lot-to-lot uniformity (19). Its utility and value to assess the release of active pharmaceutical ingredients (API) from semisolid dosage forms has been reported in numerous publications (20-32).

A simple and reproducible method using vertical diffusion cell (VDC) systems and a synthetic membrane that could be readily adopted for the quality control of semisolid products was first developed and demonstrated by Shah et al. in 1989 (22). An IVRT method for assessing the release of diclofenac dimethylamine from topical gels was developed by Goebel et al. (13). A significant difference was observed between the fluxes of the tested products. These differences in the performance of topical products were thought to be due to the influence of excipients and vehicle components and, thus, highlight the influence of excipients.

The in vitro release rates of acyclovir from generic creams approved in South African and Indian markets were evaluated and compared with the innovator products available in the respective markets using VDC, in order to determine the "sameness" of those approved generic products based on the in vitro data (15). The in vitro release comparisons were based on the recommendations described in the United States Food and Drug Administration (FDA) Draft Guidance for acyclovir ointment (16) and the SUPAC-SG Guidance for nonsterile semisolid dosage forms (17). Plots of the release rates (slopes) of the cumulative amounts of acyclovir released versus the square root of time for the various generic formulations compared with the reference product were found to be within the limits of 75.00% to 133.33% with a 90% confidence interval. These experiments indicate that the generic acyclovir cream formulations exhibited release rates that were comparable to the innovator product and could be considered pharmaceutically equivalent.

Whereas dissolution testing is considered as an important test to determine the release of non-solution products which are administered via an extravascular route (generally orally) and intended for the systemic circulation, drug release from products which are topically applied to the skin is considered equally important. Topical dermatological products, usually semisolids such as creams, ointments, emulsions, foams, gels, and lotions, amongst others, are generally intended for local action on or in the skin where the drug is not destined for the systemic circulation (33). In certain instances where a transdermal dosage form is specifically intended for local action only, IVRT should be readily applicable whereas in vitro testing of transdermal dosage forms intended for systemic absorption, in vitro penetration tests (IVPT) using various types of skin samples as the membranes may be the preferred approach. However, there can be semisolids with systemic action, and there are transdermal delivery systems with local action approved by the FDA for the United States market. Topical products intended for the systemic circulation require penetration beyond the stratum corneum and

Observe the effects of Acetylcholine on a "stabilized" rabbit-ileum:

Check List: Tick or Cross

- i. Check the temperature of the solution/ water at 37°C and mark the starting point. 1
- ii. Record the tracing of 'Normal Contractions' for 30 seconds. 2
- iii. After 30 seconds add 0.5ml of the given concentration (e.g., 1µg) of Acetylcholine without stopping the drum and observe the response for 30 seconds. 3
- iv. Now, stop the drum, wash the tissue 2 to 3 times with Tyrode's solution and wait for 2-3 minutes till the lever touches the base line. 1
- v. Label the diagram showing different steps. 1

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