it over the affected area. For intravaginal treatment, the patient uses a plastic applicator, some of which are prefilled and disposable and others reusable and filled by the patient immediately prior to use.

To fill the applicator, the closure cap is removed from the tube, the applicator screwed on in its place, and the tube gently squeezed until the applicator is filled and the plunger rises to its marked stopping point. The filled applicator is unscrewed from the tube and replaced by the cap. Inserting intravaginal products is best accomplished with the patient lying on her back or in an otherwise comfortable position. The applicator barrel is firmly grasped and inserted into the vagina as far as possible without causing discomfort. The plunger is depressed until it stops, releasing the medication in the vagina. The applicator is carefully withdrawn for washing and ultimately discarding. The patient should be instructed to wash her hands thoroughly after use.

Aerosol foams are used intravaginally in the same general manner. The aerosol package contains an inserter device, which, when attached to the canister, may be filled with foam. The filled inserter is placed in the vagina and the product delivered by pushing the plunger. Vaginal foams are oil-in-water emulsions resembling light creams. They are water miscible and nongreasy. The patient should be instructed to wash her hands thoroughly after use.

When once-a-day administration is prescribed, it is best done at bedtime for reasons of medication retention, avoidance of daytime leakage, and lessened soiling of clothing. Creams with water-washable bases are preferred to oleaginous ointments. Patients who are pregnant must not use intravaginal products except with their doctor's approval and supervision. Tampons are not to be used during intravaginal treatment.

Unmedicated lubricant jellies are used by physicians in rectal, urethral, and vaginal examinations. All products should be tightly closed when not in use to prevent contamination. If left unsealed, gels and jellies are particularly prone to dry out. Examples of vaginal ointments, creams, and gels are presented in Tables 10.2 and 10.4.

DRUG RELEASE FROM SEMISOLID DOSAGE FORMS

Semisolid dosage forms are used for either topical/local or systemic effects. If the purpose is to deliver a drug to the surface of the skin or to be absorbed into the systemic circulation, it must be capable of being released from the vehicle in a reproducible way. For uniformity of the same product from batch to batch as well as for release of the drug for absorption, it is critical that the rate of release of the drug be reproducibly determined. In vitro release testing is recommended by the FDA as a measure of "product sameness" during scale-up and postapproval changes for semisolids (SUPAC-SS).

Semisolid dosage forms can produce distinct difficulties in the development of in vitro models due to the physicochemical properties of formulations and the specific physiological environment in which they must release their API. It is important to validate a release test before using it; it must be reproducible and reliable. Even though it is not a measure of bioavailability, the test must be capable of detecting changes in drug-release characteristics from the finished product. Changes in these release characteristics may alter the biological performance of the drug in the dosage form.

Drug-release measurements for ointments, creams, and gels have been in the literature for years. Formerly, the semisolid dosage form was placed in direct contact with a receptor fluid. Today, generally a Franz diffusion cell is used where the semisolid dosage form is placed on a membrane that is situated on top of a receptor chamber containing a receptor solution. The drug is released from the dosage form and passes through the membrane into the receptor solution where it is sampled and analyzed for content. The results are plotted as the concentration of the drug in the receptor fluid versus time. The rates of drug release can be calculated and compared.