

in the protective coating that would render the container weak or subject to corrosion.

Most aluminum containers are manufactured by extrusion or by other methods that make them seamless. They have the advantage over the seam type of container of greater safety against leakage, incompatibility, and corrosion. Stainless steel is employed to produce containers for certain small-volume aerosols in which a great deal of chemical resistance is required. The main limitation of stainless steel containers is their high cost.

Plastic containers have met with varying success in the packaging of aerosols because of their inherent problem of being permeated by the vapor within the container. Also, certain drug-plastic interactions affect the release of drug from the container and reduce the efficacy of the product.

Valve Assembly

The function of the valve assembly is to permit expulsion of the contents of the can in the desired form, at the desired rate, and in the case of metered valves, in the proper amount or dose. The materials used in the manufacture of valves must be inert to the formulations and must be approved by the FDA. Among the materials used in the manufacture of the various valve parts are plastic, rubber, aluminum, and stainless steel.

The usual aerosol valve assembly is composed of the following parts (Fig. 14.13):

1. *Actuator*: the button the user presses to activate the valve assembly for emission of the product. The actuator permits easy opening and closing of the valve. It is through the orifice in the actuator that the product is discharged. The design of the inner chamber and size of the emission orifice of the actuator contribute to the physical form (mist, coarse spray, solid stream, or foam) in which the product is discharged. The type and quantity of propellant used and the actuator design and dimensions control the particle size of the emitted product. Larger orifices (and less propellant) are used for products to be emitted as foams and solid streams than for those intended to be sprays or mists.

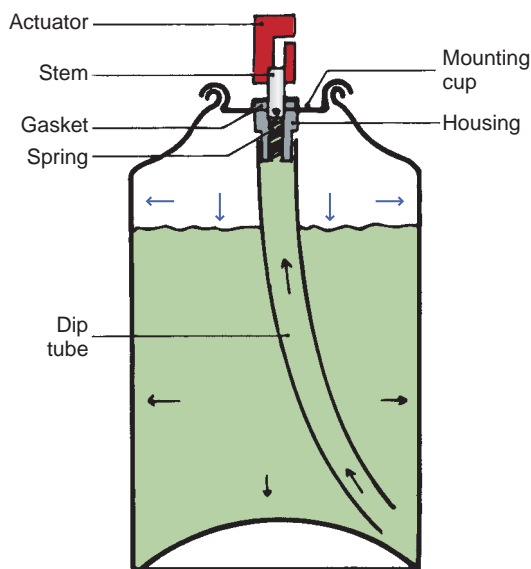


FIGURE 14.13 Valve assembly components.

2. *Stem*: supports the actuator and delivers the formulation in the proper form to the chamber of the actuator
3. *Gasket*: placed snugly with the stem and prevents leakage of the formulation when the valve is closed
4. *Spring*: holds the gasket in place and is the mechanism by which the actuator retracts when pressure is released, returning the valve to the closed position
5. *Mounting cup*: attached to the aerosol can or container and holds the valve in place. Because the underside of the mounting cup is exposed to the formulation, it must receive the same consideration as the inner part of the container with respect to meeting criteria of compatibility. If necessary, it may be coated with an inert material (e.g., an epoxy resin or vinyl) to prevent an undesired interaction.
6. *Housing*: Directly below the mounting cup, the housing links the dip tube and the stem and actuator. With the stem, its orifice helps to determine the delivery rate and the form in which the product is emitted.
7. *Dip tube*: extends from the housing down into the product; brings the formulation from the container to the valve. The viscosity of the product and its intended