are supplied as open necked containers that are sealed by fusion of the narrow glass neck after filling (see Fig. 36.4). Usually the neck of the ampoule has a painted ceramic ring on it. Due to the baking process required to fuse the ceramic to the glass, this acts as a weak point at which the ampoule can be easily snapped open by hand. The main disadvantages of glass ampoules are the fragility of the container, the potential for deposition of glass particles into the drug product on opening and the potential for injury to the fingers of the person opening the ampoule. The problem of fragility is overcome by using robust secondary packaging. Glass particles can be removed from the product by drawing up the contents of the ampoule through a filter straw or quill into a syringe. The advantages of glass ampoules are low cost and (if Type I glass is used) very little interaction between the container and the product.

Plastic ampoules are prepared using a highly automated blow-fill-seal product process. The filling machine is loaded with the drug solution to be filled and with plastic granules (polyethylene and/or polypropylene) which are then melted. The molten plastic is blown into the ampoule mould to form the body of the ampoule, the body of the ampoule is filled with product and then the lid of the ampoule is moulded onto the top of the ampoule to form a seal. All of the above happens as a single process which can take less than a second to complete (see Fig. 36.5). The sealed ampoule is opened by twisting off the lid and very few particles are generated to contaminate the product. Plastic ampoules are also much more robust than glass ampoules. Disadvantages are that this is a more costly process, and is only suitable for drug products formulated as simple solutions (for instance freeze-drying processes cannot be undertaken using plastic ampoules). A full comparison of glass and plastics as materials for pharmaceutical packaging is provided in Chapter 47.

Fig. 36.4 • Open and sealed glass ampoules.

Vials

Vials are containers usually made of Type I borosilicate glass with a re-usable synthetic rubber closure. Vials have advantages as containers as they permit multiple withdrawals and are made in sizes usually ranging from 5 mL to 100 mL. Vials are sealed with a bromobutyl or chlorobutyl synthetic rubber closure held in place by an aluminium seal crimped around the neck of the glass vial. The rubber closure (or septum) is usually protected by a plastic flip-off cap (Fig. 36.6). This acts purely as a dust cap and does not provide a covering that maintains the sterility of the septum prior to use.

To withdraw a dose from a vial, the cap is removed and the septum disinfected with a sterile alcohol wipe. A syringe and needle is used to puncture the rubber closure and remove the required amount of

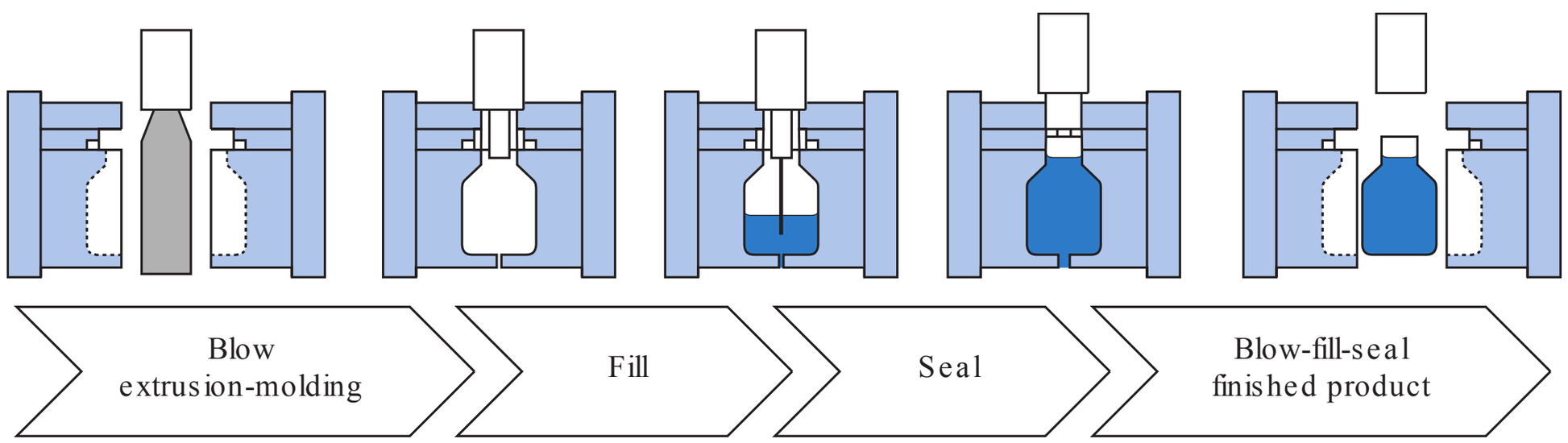

Fig. 36.5 • Blow-fill-seal process.