Table 27-2 Minimum Quantity to be Used for Each Sterility-Test Medium

Type of finished product	Quantity per container	Minimum quantity to be used (Unless otherwise justified and authorized)
Liquids	Less than 1 mL	Whole contents of each container
	1–40 mL	Half of the contents of each container, but not less than 1 mL
	Greater than 40 mL, but $\leq$ 100 mL	20 mL
	Greater than 100 mL	10% of the contents of the container, but not less than 20 mL
	Antibiotic liquids	1 mL
Insoluble preparations, creams, and ointments to be suspended or emulsified		Use the contents of each container to provide not less than 200 mg
Solids	Less than 50 mg	The whole contents of each container
	50 mg or more, but less than 300 mg	Half the contents of each container, but not less than 50 mg
	300 mg to 5 g	150 mg
	Greater than 5 g	500 mg
Others	Catgut and other surgical sutures for veterinary use	3 sections of a strand (each 30 cm long)
	Surgical dressing/cotton/gauze (in packages	100 mg per package
	Sutures and other individually packaged single use material	The whole device
	Other medical devices	The whole device, cut into pieces or dissembled

the presence of a color indicator would not be seen anyway. For oily products, FTM is slightly modified by the addition of 1 ml Polysorbate 80 to 1 liter of the media. Polysorbate 80 serves as an emulsifying agent to permit adequate dispersal of a lipophilic product in a hydrophilic growth medium.

The other primary USP/NF culture medium for the sterility testing of parenterals is called soybean-casein digest (SCD) or trypticase soy broth (TSB) medium (Fig. 27-1 shows a nonsterile

Figure 27-1 (*Left*) Sterile fluid thioglycollate medium (*Right*) non-sterile trypticase soy broth. *Source*: Courtesy of Ryan Cool, Baxter BioPharma Solutions.