

1 **TEST FOR EXTRACTABLE VOLUME OF PARENTERAL PREPARATIONS**

2 Suspensions and emulsions are shaken before withdrawal of the contents and before the determination of the
3 density. Oily and viscous preparations may be warmed according to the instructions on the label, if
4 necessary, and thoroughly shaken immediately before removing the contents. The contents are then cooled to
5 20-25 °C before measuring the volume.

6 **SINGLE-DOSE CONTAINERS**

7 Determine an appropriate number of containers to be tested, based on the number of units available and a
8 suitable statistical approach. Following the instructions on the label, extract the total contents of each
9 container selected into a suitable, dry syringe fitted with a suitable needle, e.g. a 21-gauge needle not less
10 than 2.5 cm in length. Expel any air bubbles from the syringe and needle, taking care not to spill out any
11 product. Then discharge the contents of the syringe without emptying the needle into a calibrated dry
12 cylinder (graduated to contain rather than to deliver the designated volumes) of such a capacity that the
13 volume to be measured occupies at least 40 per cent of its graduated volume. Alternatively, the volume of the
14 contents in millilitres may be calculated as the mass in grams divided by the density.

15 The volume in each container tested is not less than the nominal volume .

16 **MULTIDOSE CONTAINERS**

17 For injections in multidose containers labelled to yield a specific number of doses of a stated volume, select
18 one container and proceed as directed for single-dose containers using the same number of separate syringe
19 assemblies as the number of doses specified.

20 The volume extracted into each syringe is such that it delivers not less than the dose stated on the label.

21 **CARTRIDGES AND PREFILLED SYRINGES**

22 Determine an appropriate number of containers to be tested, based on the number of units available and a
23 suitable statistical approach. If necessary, fit the containers with the accessories required for their use
24 (needle, piston, syringe) and transfer the entire contents of each container, without emptying the needle into a
25 dry tared beaker by slowly and continuously depressing the piston. Calculate the volume in millilitres
26 calculated as the mass in grams divided by the density.

27 The volume measured in each of the container tested is not less than the nominal volume.

28 **LARGE-VOLUME PARENTERALS**

29 Determine an appropriate number of containers to be tested, based on the number of units available and a
30 suitable statistical approach. Transfer the contents of the container into a calibrated dry cylinder of such a
31 capacity that the volume to be measured occupies at least 40 per cent of its nominal volume. Measure the
32 volume transferred. Alternatively, the volume of the contents in millilitres may be calculated as the mass in
33 grams divided by the density.

34 The volume in each container tested is not less than the nominal volume.