

### 3.2.3 *Harvesting*

Harvesting of virus fluid shall be carried out by a method approved by the national control authority. No antibiotics shall be added at the time of harvesting.

Each single harvest shall be tested for sterility and virus content according to the following subsections. Each single harvest shall also be tested according to the provisions of Part A, section 3.3, unless those tests are made on the virus pool.

The samples of single harvests shall be taken for testing at the time of harvesting and if not tested immediately shall be kept at a temperature below  $-60^{\circ}\text{C}$  until tested.

#### 3.2.3.1 *Sterility tests*

A volume of at least 10 ml of each single harvest shall be tested for bacterial and mycotic sterility according to the requirements given in Part A, sections 5.2.1.2 and 5.3.1.2 of Requirements for Biological Substances No.6 (General Requirements for Sterility of Biological Substances)<sup>1</sup> as well as for mycoplasma by a method approved by the national control authority.

Tests for mycoplasma should be done using both solid and liquid media which have been shown to be capable of growing mycoplasma.

#### 3.2.3.2 *Virus titration*

The live virus content of each single harvest shall be determined by tissue-culture titration using a reference preparation of live measles virus for comparison (see Part A, section 1.3).

### 3.3 *Control of virus pools prior to clarification*

The virus pool shall be prepared from one single harvest or from a pool of single harvests and shall be submitted to the following tests unless these tests have been done on each single harvest, with the exception that even in that event, sterility tests according to Part A, section 3.3.1 shall also be done on the virus pool.

In those tests requiring prior neutralization of measles virus, the antiserum used shall not be of human, simian, canine, cavian, bovine, or avian origin. The immunizing antigen used for the preparation of the antiserum shall be produced in tissue culture cells free from extraneous microbial agents that might elicit antibodies inhibitory to the growth of any extraneous agents that may be present in the measles virus pool.

---

<sup>1</sup> *Wld Hlth Org. techn. Rep. Ser.*, 1960, 200, 15 and 17.