

1. Purpose

The test serves for proof cleanliness and determination of loosles adhering particles contaminaton of packaging.

2. Performance

The tests are performed on individual packaging.
The required cleanliness, the frequency of testing and the number of packagings to be tested are to be agreed between customer and packaging supplier.

3. Preparation for the test

- 3.1 The test samples are taken from a production batch, ready for dispatch or received, according to statistical methods.
- 3.2 The test samples are to be labeled so that they can be identified after completion of the test.
- 3.3 The closures of the test samples are to be removed.

4. Visual test

The packaging is tested visually for contaminations (e.g. rust, loose particles of lacquer, plastic abrasions). For this purpose, a lamp is placed into the packaging and the inner surface is checked completely. In the case of tight head packaging, the inside of the upper base is to be checked using a mirror. If loose particles are determined in the visual test, the test is rated as a failure.
If visual cleanliness is proven, the wipe test or rinse test is to be performed.

Determination of interior contamination of packaging**A. Wipe test****1. Test procedure**

A wipe is fixed on to a rod. The rod is moulded in the form of a ball (diameter 50 mm) at the lower end. The wipe is fixed as fold-free as possible over the end of the rod.

The rod is inserted into the packaging. With slight pressure, the inside surface is wiped twice around the entire circumference and crosswise at the centre of the inner base.

The wipe is removed from the rod; the contaminations are to be compared with a limit sample agreed between the packaging supplier and the customer.

2. Test report

The test report gives a traceable account of the type of packaging as well as data of production. The result of the visual test is documented.

The decision whether the contamination of the wipe conforms in the correct limit is noted.

The contaminated part of the wipe is to be cut out and attached to the test report.

B. Rinse test

1. Test equipment, auxiliary devices and operating supplies

1.1 Assembly, e.g. according to the drawing: *

| | |
|--|----------|
| Stainless steel tube with bevelled sucking end | pos. (1) |
| Plastic hose (solvent resistant) | pos. (2) |
| 2 litre vacuum bottle with conical bottom | pos. (3) |
| Glass base and hood with stainless steel screen plate | pos. (4) |
| Cellulose Nitrate Membrane filter, pore size 5.0 μm | pos. (5) |
| Vacuum hood with hose adapter | pos. (6) |
| Spring clamp | pos. (7) |
| Vacuum hose | pos. (8) |

1.2 Vacuum pump

1.3 Magnifying glass or microscope for counting

1.4 Rinsing liquid: water

1.5 Transparent adhesive tape, width at least 55 mm

1.6 Glass funnel

1.7 Limit samples agreed with manufacturer

(Figure see German version)

2. Sampling

Regardless of delivery scope a random test of 2 containers is to be taken.

3. Preparation for the test

Before the start of the test, the assembly is flushed with the rinsing liquid to establish a zero value.

* Assembly is exemplary. This main function is warranted by the use of qualified filters.

4. Test procedure

- 4.1 The rinsing liquid is filled into both containers.
Containers with up to 100 litres volume: 1 litre rinse liquid
Containers with more than 100 litres volume: 2 litres rinse liquid
- 4.2 The closed container is swirled in all directions.
- 4.3 The rinsing liquid is sucked out of the container and poured off over the membrane filter.
- 4.4 During the sucking procedure the container is to be kept in an inclined position with a slightly swirling movement to prevent any already dispersed particles from sinking back to the bottom of the container.

5. Test evaluation

- 5.1 Particles retained on the filter are identified according to the following criteria:
 - a) Type (traces of inner or outer varnish, metal or plastic abrasions, dust, general dirt, etc.)
 - b) Size
 - c) Number
- 5.2 For comparison purposes, a transparent adhesive tape is stuck over the dried filter tips with the adherent particles.
- 5.3 A final decision to accept or disqualify the delivery is made after a visual comparison of the actually determined grade of contamination with the agreed limit samples.