Qualifying test parameters using extraction / filtration (TecSA)

Cleanliness tests serve as a basis for assessing technical cleanliness, e.g. for

- initial sampling and evaluation
- entry and exit checks
- quality checks for cleanliness-related manufacturing processes (e.g. cleaning), monitoring process steps (e.g. surface treatment, assembly)

The **basis** for this is always **VDA Vol. 19-1 and ISO 16232**.

Overview of the procedure

Extraction method using ultrasound

The **individual parts** to be extracted are placed in a beaker which is then filled with a specific amount of **cleaning fluid**.

The cleaning fluid consists of **demineralised water** and an **added cleaner** (e.g. Eskaphor, Surtec – Note: Concentration as per manufacturer's specifications).

The cleaner should not only increase the cleaning effect but also reduce the surface tension of the medium. The **beaker is then placed in an ultrasound bath** and bombarded with ultrasound.

The aim:

The procedure loosens dirt particles from the component and these are **bound in the medium**. This medium is then **filtered** and the dirt particles are collected on the analysis filter. The filter is subsequently evaluated using the dhs-Cleanalyzer® Scan and the dhs-Cleanalyzer® software.

Preparing the workplace

Room

- Constant room temperature
- Good lighting
- Floor and surfaces that are easy to clean
- Storage areas for equipment and collecting vessels

Auxiliary equipment

- Beaker
- Sieve for collecting individual parts
- Filtration flask
- Collecting vessel
- CN filter
- Tweezers
- Gloves
- Vacuum pump
  Slide frame
- Ultrasound bath
- Ultrasound generator (not illustrated)
- Lid for ultrasound bath
- Drying cabinet (not illustrated)

Before the test begins, all selected components (random samples) and the auxiliary equipment are prepared and the parameters for the ultrasound device are set.

Preparing the test

Relevance of the blank value

Determining the blank value and maintaining a permitted limit for this **ensure** that the cleanliness test is carried out under sufficiently **clean test and environmental conditions**. This guarantees that contamination not from the test specimen does not falsify the result of the analysis.

Possible causes of additional contamination:

- Environment (air, personnel, workplace etc.)
- Test fluids and flushing fluids
- All objects which come into contact with the component and the test fluid such as vessels, test equipment, analysis filters, measuring devices etc.
- Handling while sampling the analysis

Determining the blank value

The blank value must **not exceed 10% of the required cleanliness value for the component**. The maximum permitted particle size is halved (**no particle > 50 µm**).

Test methods

The **test procedure** used here is subdivided into an **extraction** and a **filtration** phase.

Definition of extraction

Extraction refers to loosening particles from the test surface using an extraction procedure described in VDA 19-1. The extraction procedure loosens particles from the component. The loosened particles are then transferred to the test medium.
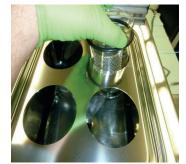
Definition of filtration

Filtration refers to the procedure in which the particles from the test medium on the analysis filter are separated out.

Carrying out a test

Extraction procedure (e.g. with ultrasound)

1. Place the individual parts to be analysed in a beaker (use sieve inserts or other tools)
2. Fill the beaker with test medium mixed to the correct concentration.
3. Place the beaker in the ultrasound bath (filled with demineralised water - use tools if necessary)
4. Check test parameters, set the parameters if necessary
5. Switch on ultrasound
6. Once the ultrasound treatment is complete, remove the beaker from the ultrasound bath
7. Cover the ultrasound bath to prevent contamination with dust and dirt

Fill beaker

Place beaker in ultrasound bath

Filtration procedure

1. Switch on vacuum pump
2. Ensure that there is a filter inside the filtration unit
3. Carefully empty the beaker into the filtration unit (ensure that no individual parts come into contact with the filter)
4. Flush the beaker with the stipulated quantity of flushing liquid and pour the flushing liquid over the components into the filtration flask. Flush the components with the defined quantity of flushing liquid
6. Remove components after flushing
7. Flush the edge of the filtration flask
8. After draining off the medium, remove the filter and allow it to dry

Place filter in filtration unit

Empty beaker into filtration unit

Filter drying methods

- Using ambient air in a Petri dish (increased waiting time)
- In an oven at approx. 85°C (for approx. 10 min.)

Using slide frame

After drying, the analysis filter should be placed in a standard slide frame for evaluation (it is advisable to place something under the filter so that it is fixed in the frame once it is closed).

Evaluating the filter

The filter is evaluated using the **dhs Cleanalyzer® Scan**. In order to do this, the wet surface of the filter is placed in the scanner pointing downwards and the lid is closed. The dhs analysis software will now evaluate the image of the filter. The extracted particles will be counted and recorded according to size classes.

Settings with the dhs software tool

Scan procedure parameters / particle analysis

- Size of the area to be analysed
- Resolution / exposure
- Black level / histogram
- Regions of interest / zoom function
- Visualisation of all particles by means of a gallery view

Save results / produce report

- Determine storage location
- Define data masks for report (e.g. analysis procedure, component, tester, department, batch number etc.)
- Produce report with particle distribution (histogram) and relevant images from the particle gallery

Decay measurement

Aim

The suitability of the extraction procedure selected must be verified through the decay measurement. In the process, a sample analysis of the relevant components which must be repeated a number of times determines whether there is a reduction in the particle load. It should be possible **to extract 90%** of all particles.

Procedure (example test with ultrasound)

- Determine blank value
- Prepare random sample, check and set test parameters
- Place test specimens and medium in beaker
- Carry out sample with one sixth of the US duration
- Flush test specimens with medium through the filter
- Flush out beaker with hand flushing bottle, flush test specimens again
- Generate and label filter (e.g. 1st filter decay curve)
- Carry out the procedure 6 times with the same parameters
- Check blank value after the test to prove that all extracted particles were collected by the test filters
- Now evaluate the 2 filters obtained using the dhs-Cleanalyzer® Scan, collect measurement records
- Evaluation of the results (preferably in table form)

Partikelklasse D	Partikelklasse E	Partikelklasse F	Partikelklasse G	Summe	Kummuliert	Anzahl in %
150	90	60	30	330	330	100
120	75	55	20	270	600	45
110	50	30	15	205	805	25,5
90	30	20	10	150	955	15.7
75	25	18	8	126	1081	11,7
74	24	9	2	109	1190	9,1

Example table structure: Particle class / Total / Cumulated / Number in %

The measurement results are entered horizontally for each measurement. The figures are then totalled and cumulated. The quantity of particles from the first measurement is 100%. The percentage is then calculated from the total and the cumulated total.

Qualification after 6x sampling

The sampling procedure is deemed **to be qualified** if the particle load after the 6th sampling procedure **is below 10%.**

For a series analysis, this means that the sum of the US time from the 6 part analyses gives the ultrasound duration for the series analysis.

Effectiveness of the decay curve

In order to check the effectiveness of the parameters determined on the basis of the decay curve, it is advisable to carry out **2x sampling as a backup**.

Qualification after 2x sampling

To ensure that there are no factors that would falsify results in the 6x sampling, it is advisable to carry out a further 2x sampling. The only difference between these 2 procedures and the series test is that they are **carried out consecutively with the same individual parts**.

Procedure for 2x sampling

- Determine the blank value
- Prepare random sample, check and set test parameters
- Place test specimens and medium in the beaker
- Carry out the sample with the US duration as in the series test
- Flush test specimens with medium through the filter
- Flush out beaker with hand flushing bottle, flush test specimens again
- Generate and label filter (e.g. 1st filter 2x sampling)

- Carry out this procedure twice without changing the parameters
- Check blank value after the test to prove that all extracted particles were collected by the test filters
- Now evaluate the 2 filters obtained using the dhs Cleanalyzer® scan, collect measurement records
- Evaluating the results: In order to evaluate the results, it is advisable to create a table.

Partikelklasse D	Partikelklasse E	Partikelklasse F	Partikelklasse G	Summe	Kummuliert	Anzahl in %
410	129	105	66	710	710	100
144	78	21	9	252	962	26,1

Example table structure: Particle class / Total / Cumulated / Number in %

Sustainability of 2x sampling

If the **result** of the 2x sampling is **less than 30% of the possible particle load**, the sampling procedure for **this component is qualified** and the corresponding **test parameters are determined** and documented.

Reproducibility of the test procedures

All parameters and configurations can be saved in profiles using the dhs-Cleanalyzer® software.

This saves time when carrying out multiple sampling.

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