VDMA Documents
Food Processing Machinery and Packaging Machinery

Aseptic Packaging Machines for the Food Industry:

Minimum Requirements and Basic Conditions for the Intended Operation

supersedes VDMA 8742

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This publication has been drawn up by the Working Party for "Interface Problems in Aseptic Machinery" in the VDMA Technical Department for Packaging Machines. It is available for downloading from WWW.VDMA.ORG/Publikationen (database 'Publikationen'). Suggestions for improvements and additions may be sent to the following address: Fachverband Nahrungsmittelmaschinen und Verpackungsmaschinen im VDMA, Lyoner Straße 18, D-60528 Frankfurt/M., fax: +49 69/6603-1211.

Foreword for the first edition

This VDMA Document is the revised version of the VDMA Sheet 8742 published in 1996. Since the first edition of this working paper, a series of documents have been produced by the VDMA Working Party 'Interface Problems in Aseptic Machinery'. All papers were published in the series of 'VDMA documents Food Processing and Packaging Machinery'. After thoroughly considering the matter, the Working Party took a majority decision to also publish the revised version of VDMA 8742 as part of this working paper series, so that the document can now be downloaded directly free of charge from the VDMA website. For the most part, the changes made by the Working Party refer primarily to editorial modifications. For example, references have been included to test specifications published by the Working Party in the meantime. The definition of aseptic packaging machines and the minimum microbiological requirements made of these machines remained unchanged. The former Appendix C 'Dependence of the number of Unsterile Packages on the Initial Microorganism Count of the Packaging Material and on the Microorganism Reduction Rate' has been deleted, to be replaced by a separate working document on 'Aseptic Performance Test' that was being prepared when this VDMA document went to print.

Foreword for the 2nd edition

This VDMA document went through routine revision in 2015. The following changes have been made compared to the first edition:

- Restructuring of the VDMA document
- Weakly acidic products are distinguished from acidic products according to the distinction made by the FDA (pH > 4.6 instead of pH > 4.5)
- Definitions have been taken from other VDMA documents
- Appendix A "Minimum microbiological requirements for hygienic filling machines of class IV" has been revised
- Appendix D "Storage regulations" has been deleted. The topic is dealt with in VDMA document 16.
- The references have been updated and amended

Please note: Performance commitments

If a contract makes reference to the present VDMA document, the requirements enumerated herein provide no guarantee of quality as defined in §444 BGB (German Civil Code). This is merely a description limited to content and performance with respect to the due deliverable. The same applies equally to the minimum requirements on machine technology set out in appendix A. Other requirements need to be explicitly regulated by contract in which the operational basic conditions are taken into account.

1 Field of application and purpose

This VDMA document aims to provide a definition for aseptic packaging machines (hygienic filling machines of Class V according to VDMA for liquid and viscous foods)[1]. The reason for this is two-fold. On the one hand, microbiological performance commitments for the aseptic part of aseptic packaging machines have to be coupled with verifiable criteria. On the other hand, there should

[1] VDMA Document 'Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application' defines five different classes of hygienic filling machines for the food industry, with the strictest requirements being made of aseptic filling machines (Class V machines). The microbiological requirements for Class IV machines are defined in VDMA Document 'Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods - Minimum Requirements and Basic Conditions for Operation in Accordance with Specification'.

preferably be an explicit explanation of the implicit microbiological minimum requirements concerning the aseptic part of such a machine for unequivocal differentiation between aseptic machines and other packaging machines.

Further, it is a concern of this VDMA document to show that proper functioning of aseptic packaging machines - contingent on the system - necessitates various requirements to be satisfied by the operator of the machine unit.

This VDMA document covers aseptic packaging machines in the sense of the definition detailed in Section 2, such as are used in the food industry. Aseptic packaging machines used in the pharmaceutical industry are not included, as the conceptual terms and requirements deviate in part considerably from those in the food industry.

The microbiological comments refer to the aseptic part of aseptic packaging machines which, as a rule, comprises four functional modules:

- Active sterilisation of the packaging material, e.g. by means of hydrogen peroxide or steam
- Sterilisation and maintaining of sterile conditions of a defined machine section
- Metering and filling
- Sealing

2 Normative references

- DIN 1672-2
- VDMA FS 2

3 Terms and definitions

Terms and definitions	Definition	Explanation
Hygienic filling machines of Class IV as per VDMA	Filling machines that fill a commercially sterile product with a pH of ≤ 4.6 with recontamination prevention into packaging that has been sterilised, usually on the machine.	This is achieved by making high demands in terms of the efficiency of the systems used to sterilise the packaging, the machine interior and the components conveying product, although these are below the requirements made of Class V machines (see VDMA document NuV No. 10).

Hygienic filling machines of Class V as per VDMA ***(aseptic filling machines)***	Filling machines that fill a commercially sterile product with a pH of > 4.6 with recontamination prevention into packaging that has been sterilised, usually on the machine.	This is achieved by making high demands in terms of the efficiency of the systems used to sterilise the packaging, the machine interior and the components conveying product, (see VDMA document NuV No.11, formerly VDMA 8742). When sterilising the packaging, microorganism reduction of at least four times the power of 10 is deemed necessary in the respective sterilisation method with suitable test microorganisms. Aseptic filling machines are typically used for filling weakly acidic and neutral products (pH > 4.6) with a long shelf life without refrigeration.
Commercially sterile product	Product free of viable microorganisms and free of organisms that can multiply in the product under normal, nonrefrigerated storage and distribution conditions.	
Commercially sterile packaging and equipment	Packaging or equipment free of viable microorganisms and free of organisms that can multiply in the product under normal, nonrefrigerated storage and distribution conditions.	Defined with reference to the FDA definition in 21 CFR 113[2]
Sterile zone of the machine interior	Zone of the machine interior in an aseptic filling machine that must be kept commercially sterile after sterilisation has taken place to prevent recontamination of the commercially sterile product during the filling process.	
Test microorganism	Microorganisms used to test the sterilisation equipment of a filling machine.	Test microorganisms should have high, defined resistance to the sterilisation method being tested; they should be easy to detect and have no public health significance. The description of a test microorganism should include the following characteristics: name, precise strain description (ATTC no. or DSM no.), batch no. (for ready spore suspensions), D-value, possibly Z-value.
Inoculation	Artificial contamination of a microorganism carrier with test microorganisms.	

[2] "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

4 Minimum requirements and basic conditions for the intended operation

Several reciprocally complementary conditions must be fulfilled to warrant aseptic operational reliability of aseptic packaging machines:

- In the abovementioned VDMA document, hygienic filling machines for food processing machinery are divided into 5 classes. Class V machines exhibit the following technical characteristics:
  - construction in accordance with DIN EN 1672-2
  - cleaning in place (CIP) for systems conveying product
  - sterilisation of the filler
  - recontamination prevention for systems conveying product[3]
  - packaging materials sterilisation and recontamination prevention of the sterilised packaging material until the pack is sealed
  - cleaning and sterilisation together with recontamination prevention of the areas exposed to product

- The packaging machine must be technically capable of reliably killing microorganisms including bacterial spores (see Appendix A, Section A.1).

- By means of appropriate control techniques, the machine manufacturer must ensure that the product to be packaged cannot be contaminated as a result of technical faults in the aseptic part of the packaging machine. If, nevertheless, such faults occur, it must be ensured that contaminated packages are either avoided or detected and discarded (see Appendix A, Section A.2).

- Suitable technical and organisational measures are required to restrict any initial microorganism contamination of packaging and the aseptic part of the filling machine to an unavoidable level (see Appendix B, Section B.1 to B.7)

- Observance of the preventive organisational measures must be ensured by way of a suitable quality assurance system implemented by the machine operating company (see Appendix B, Section B.8).

5 Other documents

VDMA Documents Food Processing Machinery and Packaging Machinery are available as downloadable file free of charge from vdma.org/publikationen.
Machine sector: Food processing machinery and packaging machinery

EHEDG documents are available from www.ehedg.org -> guidelines

EHEDG Doc. No. 46 (2016)
Aseptic and Hygienic Filling Machines – Installation, Qualification and Operation
Forthcoming;

Reuter, H.; Biewendt, H.-G.; Klobes, R.H. (Hrsg.):
Typprüfung von aseptisch arbeitenden Verpackungsmaschinen für ultrahocherhitzte Milch zum Zwecke der amtlichen Prüfung (Prüfrichtlinie Nr. 3 (1982) des Erhitzerausschusses)
Kieler Milchwirtschaftliche Berichte, Heft 4/34, Band 1982, S. 409 - 414

[3] When deploying methods using UV and light, suitable measures are also necessary to ensure that the (packaging) surfaces being sterilised and the area between the UV/light lamp and the surface being sterilised free of dust.

VDMA Doc. 1 (2011)
Two Methods for Determing Peroxide Residues in Empty Packaging at the Filling Machine – Test Procedures
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 1 / 2000; revised edition 2011
German and English

VDMA Doc. 2 (2006)
Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No.2 / 2. edition 2006
German and English

VDMA Doc. 3 (2008)
Checklist "Quality Assurance and Maintenance" for aseptic filling machines for the food industry
German and English
VDMA Documents Food Processing Machinery and Packaging Machinery No. 3 / 2. ed. 2008
German and English

VDMA Doc. 4 (2012)
Aseptic Production Lines: Unsterility Risks in Product and Feed Lines - Planning and Installation Faults
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 4 / 2002, 2. edition 2012
German and English

VDMA Doc. 5 (2002)
Signal exchange for aseptic filling machines - Minimum requirements for safe operation
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 5 / 2002
German and English

VDMA Doc. 6 (2008)
Code of Practice
Filling Machines of VDMA Hygienic Class V: Testing the Effectiveness Packaging Sterilization Devices
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 6 / 2002; 2. edition 2008
German and English

VDMA Doc. 8 (2014)
Code of Practice
Testing Aseptic Plants: Sterilizing the Sterile Zone in a Machine Interior
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 8 / 2003; 2. revised edition 2014
German and English

VDMA Doc. 10 (2016)
Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods
Minimum requirements and basic conditions for operation in accordance with specification
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 10 / 2005, 2. edition 2016
German and English

VDMA Doc. 12 (2007)
Guide to Checking the Microbiological Safety of Hygienic Filling Machines of VDMA Classes IV and V
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 12 / 2007
German and English

VDMA Doc. 14 (2006)
Code of Practice
Testing Hygienic Filling Machines of VDMA Class V - External Sterilization of Packaging Materials
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen No. 14 / 2006
German and English

VDMA Doc. 16 (2010)
General Requirements on Packaging for Filling Machines of VDMA Hygiene Classes IV and V
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen Nr. 16 / 2010
German and English

Appendix A: Minimum requirements for aseptic packaging machines

A.1 Microbiological requirements

Note 1: The test microorganisms are chosen and the microorganism reduction rate to be demonstrated for the selected test microorganism is established as a function of the sterilisation method in question. The differing sensitivity of a test microorganism to the different sterilisation methods results in different requirements for the microorganism reduction rate.

Note 2: The following list does not claim to be complete. For methods that are not listed, test conditions should be chosen that offer a comparable level of microbiological safety as the listed methods.

Note 3: Test methods for determining microorganism reduction rates are listed in Appendix D.

Packaging sterilisation (surfaces in contact with product):

Sterilisation method	**Test microorganisms, required microorganism reduction rate**
H_2O_2	Spores of Bacillus atrophaeus (ATCC 9372, DSM 675, formerly Bacillus subtilis) and Bacillus subtilis SA 22 (identical with NCA 72-52 and with DSM 4181) Microorganism reduction ≥ Log 4
Steam and hot water	Spores of the strain Geobacillus stearothermophilus NCA 1518, ATCC 7953 (identical with DSM 5934) Microorganism reduction ≥ Log 4
Peracetic acid products	Spores of Bacillus atrophaeus (ATCC 9372, DSM 675, formerly Bacillus subtilis) and Bacillus subtilis SA 22 (identical with NCA 72-52 and with DSM 4181) Microorganism reduction ≥ Log 4
Electron beam (e-beam)	Radiation dose as per ISO 11137-2 (2015) Section 6 for a sterility assurance level (SAL) of 10 to the power of minus 6 or stipulation of the target microorganism and the corresponding minimum killing rate according to the procedure in IFTPS G 005 V1 (2011) Sections 6.9.2 to 6.9.4

Sterilisation of the sterile zone of the machine interior

Sterilisation method	**Test microorganisms, required microorganism reduction rate**
H_2O_2	Spores of Bacillus atrophaeus (ATCC 9372, DSM 675, formerly Bacillus subtilis) and Bacillus subtilis SA 22 (identical with NCA 72-52 and with DSM 4181) Microorganism reduction ≥ Log 4
Water vapour	Spores of Geobacillus stearothermophilus NCA 1518, ATCC 7953 (identical with DSM 5934) Microorganism reduction ≥ Log 4
Peracetic acid products	Spores of Bacillus atrophaeus (ATCC 9372, DSM 675, formerly Bacillus subtilis) and Bacillus subtilis SA 22 (identical with NCA 72-52 and with DSM 4181) Microorganism reduction ≥ Log 4

Sterilisation of systems conveying product

Temperature-time combination for sterilisation of a cleaned machine with saturated steam or pressurised hot water: 121 °C; 30 min. for the product-conveying components of the filler (or equivalent conditions), to be measured at the coldest spot.[4]

In the case of other sterilisation media verified by test microorganisms:

Sterilisation method	**Test microorganisms, required microorganism reduction rate**
Peracetic acid products	Spores of Bacillus atrophaeus (ATCC 9372, DSM 675, formerly Bacillus subtilis) and Bacillus subtilis SA 22 (identical with NCA 72-52 and with DSM 4181) Microorganism reduction ≥ Log 5 :
Steam and hot water	Spores of Geobacillus stearothermophilus NCA 1518, ATCC 7953 (identical with DSM 5934) Microorganism reduction ≥ Log 5

A.2 Measuring, control, monitoring and safety equipment [5])

Aseptic packaging machines must be equipped

- with measuring devices to such an extent that all physical variables concerning the packaging machine which are important for safe operation can be measured, checked and recorded with adequate accuracy;

- with control devices for the packaging machine functions to such an extent that proper operation is ensured independent of fault factors (e.g. control of package material sealing);

- with monitoring and safety devices to such an extent that operational faults of the packaging machine which might affect product quality are indicated or trigger corresponding troubleshooting measures.

Faults and malfunctions resulting from the product to be packaged and its supply or from the operating company's supply and operating materials system must be ruled out by the operating company through suitable measuring, control, monitoring and safety equipment.

The measuring, control, monitoring and safety equipment must be protected to prevent unauthorised intervention.

[4] Corresponds to microorganism reduction of 5 log cycles for spores of the strain Geobacillus steathermophilus NCA 1518, ATCC 7953 (identical with DSM 5934)
[5] This section was phrased with reference to section 2.3 of the Prüfrichtlinie Nr. 3 (1982) of the Erhitzerausschuss at the Bundesanstalt für Milchforschung Kiel.

Appendix B: Basic conditions for the intended operation of aseptically operating packaging machines[6]

B.1 Machine cleaning

As a rule, aseptic packaging machines are equipped with CIP (cleaning in place) systems for automatic machine cleaning. Consistently acceptable cleaning results depend on the use of the cleaning agents recommended by the manufacturer of the machine and on compliance with the cleaning parameters, times and intervals prescribed by the manufacturer. The cleaning agents used are to be agreed by the user with the manufacturer of the machine and depend on the nature of the product to be packaged.

The use of unsuitable cleaning agents can damage materials and impair the aseptic functions of the machine.

B.2 Sterilisation of the machine

As a rule, aseptic packaging machines are equipped with SIP (sterilisation in place) systems for automatic sterilisation of the aseptic part of the machine. Perfect sterilisation presumes compliance with the sterilisation intervals and sterilisation parameters specified by the manufacturer.

B.3 Machine maintenance

Perfect cleaning and sterilisation of the aseptic packaging machine depends on strict observance of the maintenance tasks and cycles laid down by the manufacturer. This also applies in particular to the use of original spare parts and to compliance with the storage conditions recommended for elastomers. Maintenance and servicing tasks may only be carried out by appropriately qualified and trained personnel.

B.4 Storage of packaging materials

Packaging materials to be processed on aseptic packaging machines should be stored and transported under conditions which prevent contamination of the packaging materials by microorganisms. Storage of the packaging materials for excessively long periods must be ruled out. As a rule, machine and packaging material manufacturers issue recommendations for the specific packaging material.

B.5 Requirements concerning the operating personnel - training and hygiene

As part of the GMP (good manufacturing practice) rules of the operating company, contamination of packaging materials by operating staff should be prevented and operating errors by suitable measures, particularly by providing corresponding staff training.

B.6 Requirements for the product to be filled

For aseptic operation of the packaging machine, the operating company must ensure that only sterile product enters the packaging machine for packaging during the production process.

[6] Further information can be found in VDMA Document No. 3 and EHEDG Doc. No. 46 (2016)

B.7 General requirements on the local environment of an aseptic packaging machine

The operating company should provide a suitable local environment (factory area, operating resources, qualified and trained operating and maintenance staff, etc.).

Note: Corresponding information can be found in EHEDG Doc. No. 46 (2016)

B.8 Requirements for the quality assurance system of the operating company

The operating company should maintain a suitable quality assurance system which describes suitable measures for meeting the requirements set out under B.1 to B.7 and ensure and document its application.

Appendix C: Test procedures for ascertaining the microorganism reduction rates in aseptic packaging machines

The following codes of practice describe test procedures for ascertaining the microbiological efficiency of aseptic machines with packaging sterilisation devices. These are so-called challenge tests using artificial packaging contamination and controlled marginal conditions in order to obtain statistically meaningful and objectively comparable test results. Choosing a test microorganism suitable for the specific sterilisation process is of special significance. The choice is based on resistance of the microorganisms and their spores to the sterilisation medium.
These tests differ fundamentally from so-called 'Aseptic Performance Tests'[7] which are carried out before releasing an aseptic filling machine for commercial production. These tests serve to verify the microbiological reliability of the filling machine under realistic production conditions and therefore do not include any artificial contamination with test microorganisms.

The listed codes of practice are available for downloading from http://www.vdma.org/publikationen (database 'Publikationen').

Merkblatt
Prüfung von Aseptikanlagen mit Packmittelentkeimungsvorrichtungen auf deren Wirkungsgrad
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen Nr. 6
German and English

Merkblatt
Prüfung von Aseptikanlagen: Entkeimung des Sterilbereichs des Maschineninnenraums
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen Nr. 8
German and English

Merkblatt
Prüfung von hygienischen Abfüllmaschinen der Klasse V nach VDMA (aseptisch arbeitende Abfüllmaschinen) – Außenentkeimung von Packmitteln
VDMA-Fachverbandsschriften Nahrungsmittelmaschinen und Verpackungsmaschinen Nr. 14
German and English

[7] A further publication on the 'Aseptic Performance Test' is planned in the series of 'VDMA Documents Food Processing and Packaging Machinery'.