Product Information Package

PRODUCT NAME	D(-)-MANNITOL PH.EUR./USP
PRODUCT CODE	25311
GRADE	PH.EUR./USP
VERSION	2
DATE	23-06-2025

VWR International bv – Part of Avantor
Researchpark Haasrode 2020 - Geldenaaksebaan 464 - B-3001 Leuven
www.vwr.com

Table of Contents

1. General Information

VWR Part Number	25311
VWR Product Name	D(-)-MANNITOL PH.EUR./USP
CAS number	69-65-8
Origin	Vegetable

2. Regulatory Information

Is the finished product compliant with the following Pharmacopoeia monographs?	
• Ph. Eur.	Yes
• USP	Yes
• JP	Not tested
• BP	Not tested
• NF	Not tested
• Other (see statement)	N/A
Does VWR hold any regulatory file (CEP, DMF) on the product?	No

3. Supply Chain

With respect to the product in question, does VWR perform:	
• Production	No
• Filling, packaging, relabeling	Yes
• Quality Control	Yes
• Storage and Distribution	Yes
State the name and address of the original manufacturer The original manufacturer of the material can be made available upon request. The name and address will be disclosed subsequent to the signing of a confidentiality agreement with VWR.	
If VWR is not the original manufacturer, is the product delivered to VWR:	
• Directly from manufacturer?	No
• Always from the same manufacturing site?	Yes
• From an approved supplier	Yes
For a detailed supply chain description see the Supply chain statement in attachment	

4. Manufacturer

Is the manufacturer certified according to	
• ISO 9001	Yes
• ISO 14001	Yes
• GMP	Yes
• EXCiPACT	No
• Other	ISO 45001, FSSC 22000
Is the production site dedicated for the product?	No
If not, other products?	Carbohydrates
• Are materials that are high effective substances and/or toxic produced on the same manufacturing site?	No
• Are hormones produced on the same manufacturing site?	No
• Are beta-lactam antibiotics produced on the same manufacturing site?	No
• Are cytostatics produced on the same manufacturing site?	No
Is the production process continuous or batch driven?	Continuous

5. Filling and Packaging

State the VWR Filling and Packaging site: VWR International bv - Part of Avantor, Researchpark Haasrode 2020, Geldenaaksebaan 464, B-3001 Leuven, Belgium	
What quality system is applied to this product?	
• ISO 9001	Yes
• ISO 14001	Yes
• ISO 45001	Yes
What level of GMP is applied to this product?	See GMP statement
All certifications of the production site:	
• ISO 9001	Yes
• ISO 14001	Yes

• ISO 45001	Yes
• EU-GMP (limited product scope)	N/A
• ISO17034 (limited product scope)	Yes
Describe the quality management system: The Quality Management System is described in detail in our Self Assessement.	
Is the product filled under controlled conditions?	
• At least Cleanroom ISO Class 8 at rest (0.5µm; 5µm)	Yes
• Laminar flow	No
Is the filling process automated or manual?	Manual
Is the filling room dedicated or multiproduct during filling?	Dedicated
Is a gowning procedure followed to enter the cleanrooms?	Yes
Do you have a system for reconciliation of labels?	Yes
Can a batch be traced back to :	
• The bulk material	Yes
• QC release	Yes
• Filling documents	Yes
How long are batch records retained? Records are retained for at least one year past the expiry date.	
What type of water is used for cleaning purposes? Potable water and final rinse with Purified water compliant to EP and USP.	
What is your definition of a batch? A batch is defined as a product volume produced from one manufacturer batch during a fixed period of time	
Lot number system? VWR lot numbers are unique nine digit alpha-numeric codes comprised of the following; The first two numbers are the last two digits of the year of issuing the filling order. The letter indicates the month (A=Jan, B=Feb, etc.) in which the filling order was issued. The next two numbers indicate the day of printing of the filling order. Finally, the last four digits increase sequentially. This allows to estimate the period in which the product was filled.	

6. Certificate of Analysis (COA)

Which information is stated on the VWR COA	
• VWR Article number	Yes
• Product name	Yes
• Batch number	Yes
• Expiry date	Yes
• Production date	Yes
• Filling date	No
• Specifications	Yes
• Results	Yes
• Electronic signature of QC Manager	Yes

7. Shelf Life

What is the shelf life of the product?	60 months
How is the expiry date attributed?	Copied from manufacturer
Is the stated shelf life based on	
• Stability testing	Manufacturer information
• Retesting retained samples	No
• Literature	No
• Historical data	No

8. Label

Which information is stated on the VWR product label?	
• VWR product code	Yes
• Product name	Yes
• Batch number	Yes
• Expiry date	Yes
• Production date	No
• Filling date	No
• Address of the VWR filling site	Yes
• Specifications	No
• Results	Yes

9. Product Information

We point out that VWR International does not perform these specific testing on the product. But to the best of our knowledge, taking into consideration the raw materials used and/or the manufacturing process, the product is expected to be free from:

Dioxines	Yes
Mycotoxins	Yes
Phtalates	Yes
Melamine	Yes
Aflatoxin	No information available
Nanomaterials	Yes
Asbestos	No information available
Latex	Yes
Carcinogenic, mutagenic and reprotoxic substances	No information available
Pesticide	Yes

10. Product Documentation

Specification	Available on www.VWR.com
SDS	Available on www.VWR.com
BSE/TSE Statement	Available
GMO Statement	Available
Residual solvent Statement	Available
Residual Metal Catalyst and Elemental Impurities	Available
GMP Statement	Available
Nitrosamine statement	Available
Allergen Statement	Available
VWR Filling and Packaging Process Flow	Available
Manufacturing Process Flow	Available
Supply chain statement	Available
Packaging specifications	Available
Other	N/A

Product Statements

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BSE/TSE

With reference to guideline EMA/410/01 Rev. 3 of the EC, we declare that this product is manufactured without the use of raw materials of animal or human origin.During processing the product does not come in contact with animal material. Therefore the product is considered safe regarding TSE and BSE.

GMO

With reference to Regulation 1829/2003 and 1830/2003 concerning the labeling and traceability of genetically modified organisms (GMO) and of food and feed produced from genetically modified organisms, we hereby declare that this product is neither produced from, nor consists of genetically modified organisms. Hence, to the best of our knowledge, there is no objective reason to suspect a risk associated with GMO in the product.

Allergen

To the best of our knowledge, taking into consideration the raw materials used and the manufacturing process, allergenic products according to Regulation (EU) No 1169/2011 Annex II are not expected to be present in the final product except for

Cereals ;

For your information, the allergenic products included in Regulation (EU) No 1169/2011 Annex II are:

- Cereals containing gluten and products thereof;
- Crustaceans and products thereof;
- Eggs and products thereof;
- Fish and products thereof;
- Peanuts and products thereof;
- Soybeans and products thereof;
- Milk and products thereof (including lactose);
- Nuts and products thereof;
- Celery and products thereof;
- Mustard and products thereof;

- Sesame seeds and products thereof;
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg;
- Lupin and products thereof;

We point out that VWR International does not perform any testing on allergens in the product.

Residual Solvents

With reference to guideline ICH Q3C, we hereby confirm that residual solvents are not likely to be present.

Residual Metal Catalyst and Elemental Impurities

Based on the implementation of ICH Q3D into the European Pharmacopoeia and US Pharmacopoeia, all elements from ICH Q3D Class 1 and 2A (i.e. Cd, Pb, As and Hg plus Co, V and Ni) are listed on our certificates of analysis and limits of their maximum ppm concentration will be shown. In addition, the elements of class 2B or 3 are reported in case they are intentionally added within the manufacturing process.
Those elements are analyzed by atomic absorption spectroscopy or inductively coupled plasma using optical emission spectroscopy or mass spectroscopy detection.

Based on the results gathered so far, we implemented skip lot testing for the metal catalyst residues. This means we will perform a full analysis on the residues of metal impurities every 5 lots or at least every 2 years if not ordered at high frequency. In case skip lot testing is applied for metal catalyst analysis of a concerned lot, the results of the latest performed analysis will be copied.
This process will not have any impact on the certificate of analysis and we will continue to report the elements of class 1 and 2A. Class 2B or 3 are reported in case they are intentionally added within the manufacturing process.

The specification were set based on our quantitation limits of the ICP method. The risk of having a non-compliant result reported is mitigated by;
- Qualified source (compendial grade) with ICH Q3D statement
- Enough data have been gathered over the last 5 years to support skip lot testing
- A full analysis is performed every 5 lots or at least every 2 years for less frequent orders
- In case a metal of class 1 and 2A is a specification set by the monograph, we will test it and not apply skip lot testing
- The ICHQ3D guideline does not state that we need to measure the residues of metal catalysts on each lot.

GMP

Our pharma-grade materials are prepared according to principles of good manufacturing practice (GMP). These principles are expected to be applied for the manufacture and repack of products with a designation of a pharmacopoeia in the title of the substance. The applied principles of GMP for pharmaceutical products are based on IPEC - PQG Joint Good Manufacturing Practices Guide for Pharmaceutical Excipients.The IPEC - PQG GMP Guide is also the basis for our supplier audits. Processes are verified to comply with an adequate quality level of manufacturing and quality control.We trust that the applied GMP principles cover the quality management system and the extent of GMP necessary throughout manufacturing processes for pharma-grade products.

Nitrosamine

Following an internal evaluation in accordance with regulatory authority guidance and as outlined in the ICH Q9 guideline on quality and risk management, VWR International bv ("VWR") has determined that nitrosamines and related compounds are not likely to be present above reportable limits in this product.

VWR's review of the products for risk of nitrosamines included the assessment of potential nitrogen sources and other chemistries with potential for nitrosamine impurity formation. Following such assessment, in line with the CHMP Assessment report of Article 5(3) of Regulation EC (No) 726/2004 (EMA/369136/2020) by the European Medicines Agency, dated 25 June 2020, VWR is able to confirm the following:

1. None of our manufacturing processes utilize sodium nitrite or other nitrosating agents as intentionally added ingredients in the presence of secondary, tertiary amines or quaternary ammonium salts within the same or different manufacturing step.

2. None of our manufacturing processes utilize sodium nitrite or other nitrosating agents as intentionally added ingredients in combination with reagents, solvents or catalysts, which are susceptible to degradation to secondary or tertiary amines, within the same or different manufacturing step.

3. During our manufacturing process the products are not coming into contact with nitrosamines or nitrosamines containing products.

4. During our manufacturing process the products are not coming into contact with equipment used to handle nitrosamines or nitrosamines containing products.

5. We do not outsource any nitrogen containing solvents or other nitrogen containing reagents to third parties for recovery or reprocessing.

6. None of our products are sold in blister packaging containing nitrocellulose printer primer that may react with amines in printing ink to potentially generate nitrosamines.

7. The water used to manufacture the products and clean the equipment has not been treated with chloramine or chlorine.

Considering the very low potential for the presence of nitrosamine in VWR manufactured and/or repacked products as set forth above, no specific testing was or is intended to be performed by VWR to confirm the absence of nitrosamine or related compounds in the products.

VWR Filling and Packaging Process Flow

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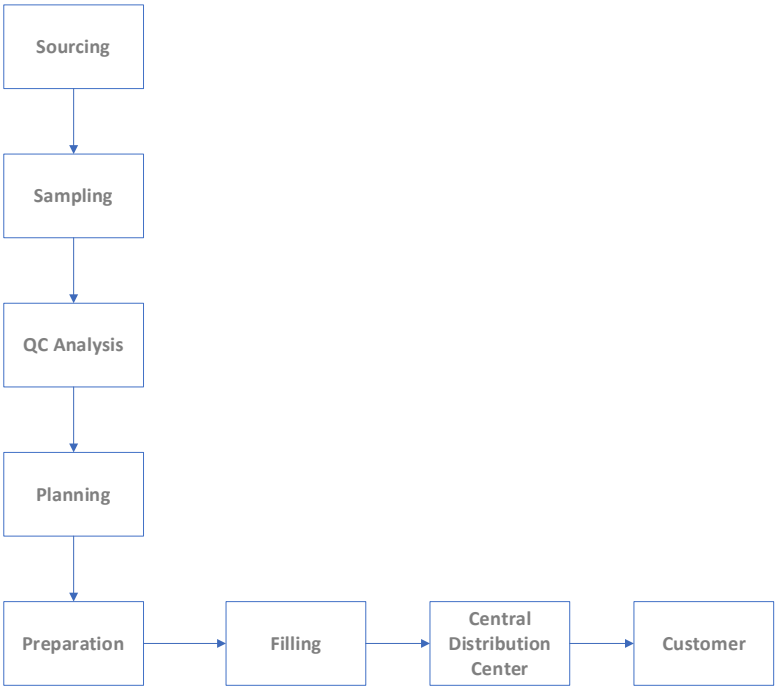
The flowchart below gives an overview of the filling and packaging flow at VWR International.



Manufacturing Process Flow

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The flowchart below gives an overview of the manufacturing process at the manufacturer.

Supply chain Flow

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With the regard to this product, we hereby confirm that the current supply chain of the product is as follows:

Company	Activity
Original Manufacturer	Manufacturing ;QC testing ;Labelling ;Warehousing ;Distribution ;
Supplier	Warehousing ; Distribution ;
VWR International bv Researchpark Haasrode 2020, Geldenaaksebaan 464, B-3001 Leuven Belgium	QC testing ;Repacking ;Labelling ;
VWR Distribution Warehouses	Warehousing ; Distribution ;

Depending on the customer requirements, various VWR warehouse can be added to the supply chain.

Packaging Specifications

25311 D(-)-MANNITOL PH.EUR./USP

Part number:	25311.297
Packed quantity:	1 KG
Primary Container	
Type	BOTTLE UN X SOLIDS
Measurements	2,5L DIN80
Material	HDPE WHITE
Secondary Container	
Type	N/A
Material	N/A
Primary Closure and Seal	
Type	SCREW CAP WITH.C. UN
Measurements	DIN80
Material	PP BLUE
Secondary Closure	
Type	N/A
Material	N/A

Packaging Specifications

25311 D(-)-MANNITOL PH.EUR./USP

Part number:	25311.366
Packed quantity:	5 KG
Primary Container	
Type	DUSTFREE BAG (10/2011/EU & 1935/2004/EU)
Measurements	400X600MMX80µM
Material	PE
Secondary Container	
Type	BUCKET 10L UN Y (10/2011/EU & 1935/2004/EC)
Material	PP WHITE
Primary Closure and Seal	
Type	CABLE TIE (STRAP)
Measurements	N/A
Material	PLASTIC
Secondary Closure	
Type	COVER FOR BUCKET 10L UN (290MM)
Material	PP BLUE

Packaging Specifications

25311 D(-)-MANNITOL PH.EUR./USP

Part number:	25311.468
Packed quantity:	25 KG
Primary Container	
Type	DUSTFREE BAG (10/2011/EU & 1935/2004/EU)
Measurements	900X720MMX100µM
Material	PE
Secondary Container	
Type	BUCKET 50L UN Y (10/2011/EC & 1935/2004/EC)
Material	PP WHITE
Primary Closure and Seal	
Type	CABLE TIE (STRAP)
Measurements	N/A
Material	PLASTIC
Secondary Closure	
Type	COVER FOR BUCKET 50L UN (440MM)
Material	PP BLUE

This document is created based on the information kept in our quality database.

By QA VWR chemicals - Charlotte Delgouffe
On June 24, 2025