



Certificate of Analysis



Material	VWRB3441-1KG
Material description	D-Galactose
Grade	Ph.Eur./NF/ENDOTOXIN TESTED
Lot	171075223
Expiration Date	2018 Apr 21
CAS Number	59-23-4
Molecular formula	C ₆ H ₁₂ O ₆
Molecular mass	180.16
Date of manufacture	2016 Oct 21
Made in	USA
Storage	Store between 15° C and 30° C.
Supplier	51984

Characteristics	Specifications	Measured values
Appearance:	.	.
White or almost white crystalline powder	Passes test	Passes test
NF specifications:	.	.
Appearance of solution	Passes test NF	Passes test NF
Identification A (IR)	Passes test NF	Passes test NF
Identification B	Passes test NF	Passes test NF
Spec.opt.rot.(20°C)(on anhydrous) [NF]	78.0 → 81.5 °	79.6 °
Acidity	Passes test NF	Passes test NF
Water [NF]	Max. 1.0 %	0.1 %
Residue on ignition [NF]	Max. 0.1 %	Max. 0.1 %
Ba (Barium)	Passes test NF	Passes test NF
Limit of lead [NF]	Max. 0.5 µg/g	0.1 µg/g
Escherichia coli [NF]	Absent	Absent
Pseudomonas aeruginosa [NF]	Absent	Absent
Salmonella [NF]	Absent	Absent
Staphylococcus aureus [NF]	Absent	Absent
Total aerobic microbial count [NF]	Max. 1000 CFU/g	Passes test
Total combined yeasts and molds [NF]	Max. 100 CFU/g	Passes test
Ph.Eur. specifications:	.	.
Assay (calculated on anhydrous)[Ph.Eur.]	97.0 → 102.0 %	99.3 %
Identification A (IR)	Passes test Ph.Eur.	Passes test Ph.Eur.
Appearance of solution	Passes test Ph.Eur.	Passes test Ph.Eur.
Acidity or alkalinity	Passes test Ph.Eur.	Passes test Ph.Eur.
Proteins [Ph.Eur.]	Max. 0.1 mg/ml	Max. 0.1 mg/ml
Related substances [Ph.Eur.]:	.	.
Sum of impurities A and B [Ph.Eur.]	Max. 1.0 %	Max. 1.0 %
Unspecified impurities [Ph.Eur.]	Max. 0.3 %	Max. 0.3 %
Total [Ph.Eur.]	Max. 2.0 %	0.1 %

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For further manufacturing use only. Not for use as an Active Pharmaceutical Ingredient.



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Characteristics	Specifications	Measured values
Reporting threshold [Ph.Eur.]	Max. 0.2 %	Max. 0.2 %
Ba (Barium)	Passes test Ph.Eur.	Passes test Ph.Eur.
Pb (Lead) [Ph.Eur.]	Max. 0.5 ppm	0.1 ppm
Water [Ph.Eur.]	Max. 1.0 %	0.1 %
Sulphated ash [Ph.Eur.]	Max. 0.1 %	Max. 0.1 %
Microbial contamination (TAMC) [Ph.Eur.]	Max. 100 CFU/g	Passes test
Bacterial endotoxins	Max. 10 EU/g	Passes test

Signature

We certify that this batch conforms to the specifications listed above.

This document has been produced electronically and is valid without a signature.

Anand Matta, Head of Laboratory - Aurora
VWR Chemicals, LLC, 220 Lena Dr., Aurora, OH 44202, USA

The following Class 1, 2 or 3 Solvents may be present in this product and are identified and quantified below. All comply with the limits prescribed in the current USP/ENDOTOXIN TESTED GRADE.

Class: Class 2, Solvent: Methanol, Concentration Limit (ppm): 100

Class: Class 3, Solvent: Ethanol, Concentration Limit (ppm): 500

Class: Class 3, Solvent: Methyl isobutyl ketone, Concentration Limit (ppm): 500

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