

Certificate of Analysis

Product:	Glucose 5%	Batch No.:	223328142
Article No.:	3642519	Revision level:	01
Solution No.:	0004	Marketing Auth. No.:	4162/2004/01-02-03
Importing country:	Romania	Manufacturing date:	2022-08-16
Strength/potency:	Glucose 5 %	Expiry date:	07.2025
Package size and type:	500 mlEcoflac plus		
Dosage form:	Solution for infusion		
Marketing authorization holder:	B. Braun Melsungen AG Carl-Braun-Strasse 1 DE 34212 Melsungen	Name/Address of manufacturer:	B. Braun Melsungen AG Carl-Braun-Str. 1 DE 34212 Melsungen

Number of Manufacturing Authorization License or Certificate of GMP Compliance of a manufacturer: DE HE 01 MLA 2021 0038 issued by Regierungspräsidium Darmstadt

Comments / remarks: None

Characteristics	Requirement	Result
Identity: Glucose	7480199.9	complies
Appearance of the solution	complies	complies
Extractable volume	>= Nominal volume	complies
pH	3,5 to 5,5	4,6
Degree of colouration of solution	not more intensely coloured than reference solution B9	complies
Clarity and degree of opalescence	<= 3 NTU	complies
5-Hydroxymethylfurfural	<= 0,25	0,03
Glucose	47,5 to 52,5 g/l	50,1 g/l
Subvisible particles >= 10 µm	<= 25 Partic./ml	complies
Subvisible particles >= 25 µm	<= 3 Partic./ml	complies
Sterility	Controlled by approved real time release testing.	complies
Bacterial endotoxins	<= 0,25 IU/ml	complies

B.Braun Melsungen AG
Quality Control

Dörthe Feuersenger

Batch Release Certificate

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Batch Release Certificate

Certification statement:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the European Community and with the specifications in the Marketing Authorization of the product or any other applicable conditions. The lot processing, packaging and analysis records were reviewed and found to be in compliance with the GMP requirements.

B.Braun Melsungen AG
Quality Assurance

K. Rieck, Qualified Person

****End of Batch Release Certificate****