

TECHNICAL DATA SHEET

1051-TDS-ENG-2023

GLUCOSA ANHIDRA (DEXTROSA) Ph. Eur.			
DESCRIPTION DCI:		DESCRIPTION DOE:	
CAS Nº: 50-99-7	EC Nº: 200-075-1		AEMPS CODE:
MOL. WEIGHT: 180.15	MOL. FORMULA: C6H12O6		ARTICLE CODE: 1051

ATTRIBUTES SHOULD BE

Appearance White or almost white, crystalline powder

Solubility Freely soluble in water, very slightly soluble in ethanol (96 %)

Identification ACompliesIdentification BCompliesIdentification EComplies

Appearance of solution Clear and not more intensel coloured than ref. sol. BY7

Specific optical rotation +52.5 / +53.3Conductivity $= < 20 \mu S \cdot cm-1$

Related substances

Sum impurities A and B =< 0.4 % =< 0.2 % Impurity C Impurity D =< 0.15 % Unspecified impurities =< 0.10 % Total impurities =< 0.5 % Dextrin Complies Soluble starch, sulfite =< 15 ppm Water =< 1.0 % Assay 97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the containers tightly closed in a fresh and dry place.

REMARKS

Glucose is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.