

TECHNICAL DATA SHEET

3968825-TDS-ENG-2023

NICOTINAMIDA ADENINA DINUCLEOTIDO (beta-NAD)			
DESCRIPTION DCI:		DESCRIPTION DOE:	
CAS N°: 53-84-9	EC N°: 200-184-4		AEMPS CODE:
MOL. WEIGHT: 663.43	MOL. FORMULA: C21H27N7O14P2·xH2O		ARTICLE CODE: 3968825

ATTRIBUTES SHOULD BE

Complies

Appearance White to off-white powder

 Purity
 => 98.0 %

 Sodium content
 =< 1 %</td>

 Water
 =< 5 %</td>

 pH
 2.0 - 4.0

 Ethanol
 =< 1000 ppm</td>

Heavy metals

Identification

Lead = < 0.1 ppmMercury = < 0.1 ppmCadmium = < 0.2 ppmArsenic = < 0.1 ppm

Microbiological control

TAMC = < 500 CFU/g

TYMC = < 50 CFU/g

Coliforms = < 0.92 MPN/g

Staphylococcus aureus Absence/25g

Salmonella Absence/25g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Sealed package, store in dry and dark at room temperature.

REMARKS

Product intended for pharmaceutical purposes.

beta-Nicotinamide adenine dinucleotide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

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.