

TECHNICAL DATA SHEET

M010254-TDS-ENG-2026

ADENOSILCOBALAMINA (USP)		
		DESCRIPTION DOE: ADENOSILCOBALAMINA
CAS Nº: 13870-90-1	EC Nº: 237-627-6	AEMPS CODE: 156H
MOL. WEIGHT: 1579,58	MOL. FORMULA: C72H100CoN18O17P	ARTICLE CODE: M010254

ATTRIBUTES	SHOULD BE
Identification A	Complies
Identification B	Complies
Identification C	Complies
Assay	96.0 - 102.0 %
Impurities	
Hydroxocobalamin	=< 1.0 %
Cyanocobalamin	=< 2.0 %
Methylcobalamin	=< 2.0 %
Individual unspecified impurities	=< 2.0 %
Total impurities	=< 5.0 %
Water	=< 12.0 %

COMPLIES WITH

USP 2026

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light. At a temperature between 2 - 8 °C.

REMARKS

Cobamamide is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.