

TECHNICAL DATA SHEET

46433156-TDS-ENG-2025

GS-441524 (USO VETERINARIO)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 1191237-69-0	EC Nº: 857-885-9	AEMPS CODE: ---
MOL. WEIGHT: 291,26	MOL. FORMULA: C12H13N5O4	ARTICLE CODE: 46433156

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Agua (K.F.)	=< 0.5 %
Any impurity	=< 0.3 %
Residue on ignition	=< 0.3 %
Assay	=> 98.0 %
Residual solvents	
Methanol	=< 3000 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
S. Aureus	Absences/1g
E. Coli	Absence/1g
C. Albicans	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

GS-441524 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.