

(6S)-5-Methyltetrahydrofolic acid, Glucosamine Salt

PRODUCT SPECIFICATIONS



Code: O-F07

Ed. 008

Date: August 21, 2019

Molecular Formula: C₂₀H₂₃N₇O₆ (C₆H₁₄NO₅)₂

Molecular Weight: 817.80

TESTS	SPECIFICATIONS	ANALYTICAL METHOD REFERENCE
Appearance	Creamy to light brown powder	Visual
Identification (IR)	Spectrum comparable with the reference standard	USP <197A>
Water content (K.F.)	≤ 8.0 %	USP <921> Method Ia (Reagents for aldehydes and ketones)
Glucosamine assay on d.b. (HPLC)	34 – 46 %	GN QT-005
5-Methyltetrahydrofolic acid assay on d.b. (HPLC)	54 – 59 %	GN QT-001
Related substances (HPLC):		GN QT-002
- 4-Aminobenzoylglutamic acid (ABGA)	≤ 0.3 %	
- 4α-Hydroxy-5-methyltetrahydrofolic acid (HOMeTHFA)	≤ 1.0 %	
- (6S)-Pyrazino-s-triazine derivate [(6S)-Mefox]	≤ 0.3 %	
- 5-Methyltetrahydropteroic acid (MeTHPA)	≤ 0.3 %	
- Any other individual impurity	≤ 1.0 %	
- Total impurities	≤ 2.5 %	
Lead	≤ 0.5 ppm	USP <233> / Ph.Eur. 2.2.57 or 2.2.58
Cadmium	≤ 0.5 ppm	USP <233> / Ph.Eur. 2.2.57 or 2.2.58
Mercury	≤ 0.1 ppm	USP <233> / Ph.Eur. 2.2.58
Arsenic	≤ 1.5 ppm	USP <233> / Ph.Eur. 2.2.57 or 2.2.58
Boron	≤ 10 ppm	USP <233> / Ph.Eur. 2.2.57 or 2.2.58
Diastereoisomeric purity (HPLC): (6S)- 5-Methyltetrahydrofolic acid	≥ 99.0 %	GN QT-003
Microbial limits:		
- Total viable aerobic count	≤ 10 ² CFU/g	USP <2021>
- Total combined yeasts & molds	≤ 10 ² CFU/g	USP <2021>
- E. coli	Absent / 10 g	USP <2022>

Packing: LDPE bags put inside of aluminum compound foil bags sealed under vacuum.

Packing size: 0.1 kg, 0.5 kg, 1 Kg, 5 Kg

Re-testing period: 24 months when stored below 25 °C

Gnosis Spa
Quality Management

