(6S)-5-Methyltetrahydrofolic acid, Glucosamine Salt **PRODUCT SPECIFICATIONS**



Description: Creamy to light brown powder

TESTS	SPECIFICATIONS	ANALYTICAL METHOD REFERENCE
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)
(6S)-5-Methyltetrahydrofolic acid, Glucosamine Salt assay on d.b. (HPLC)	96 – 105 % (equivalent to 54 – 59 % of (6S)-5-Methyltetrahydrofolic acid)	GN QT-001
Impurities: - Individual - Total	≤ 1.0 % ≤ 2.5 %	GN QT-002
Heavy metals (as Pb)	≤ 10 ppm	USP <231> Method II
Lead	≤ 1.0 ppm	USP <233>
Cadmium	≤ 0.5 ppm	USP <233>
Mercury	≤ 0.1 ppm	USP <233>
Arsenic	≤ 1.5 ppm	USP <233>
Diastereoisomeric purity (HPLC): (6S)- 5-Methyltetrahydrofolic acid	≥ 99.0 %	GN QT-003
Microbiological purity: - Total viable aerobic count - Total combined yeasts and molds - E. Coli - Salmonella sp S. aureus	$\leq 10^3$ CFU/g $\leq 10^2$ CFU/g Absent / 10 g Absent / 10 g	USP <2021> USP <2021> USP<2022> USP<2022> USP<2022>

Storage conditions: Stored in the unopened original packaging at a temperature below 25 °C, the product is stable for the

entire re-testing period.

Re-testing period: 18 months

Packing: LDPE (low-density polyethylene) bags put inside of aluminium compound foil bags sealed under

vacuum.

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

Certifications: Kosher (KOF-K Kosher Supervision), Halal (HIA)

Code: 0-F05 Ed.009

Date: January 12, 2015

Gnosis S.p.A.Corporate QA Director

