

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

PRODUCT SPECIFICATIONS



Code: 0-F07

Ed. 008

Date: August 21, 2019

Molecular Formula: $C_{20}H_{23}N_7O_6$ ($C_6H_{14}NO_5$)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 % | |
| - 4 α -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