

LEPIVITS Belgium
4 Avenue Franklin – Unité 16
1300 Wavre
BELGIQUE



Fiche technique – Fer Forte

Code EAN : 5414003238127 (60 gélules)
*NUT : 3760/20

Quatrefolic

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



PRODUCT SPECIFICATIONS

Molecular Formula: $C_{20}H_{23}N_7O_6$ ($C_6H_5N_5O_2$)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

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



ALLERGEN LIST

Relevant allergens/intolerance components potentially present in the above product are listed below, in accordance with the Annex II of Regulation (EU) 1169/2011 and the U.S.A. "Food Allergen Labeling and Consumer Protection Act of 2004".

MAJOR ALLERGENS

	Presence of allergene		Product		Line		Site	
	Yes	No	Yes	No	Yes	No	Yes	No
Peanuts and products thereof		X		X		X		X
Soybeans and products thereof		X		X		X		X
Eggs and products thereof		X		X		X		X
Nuts and products thereof		X		X		X		X
Fish and products thereof		X		X		X		X
Crustaceans and products thereof		X		X		X		X
Cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, khorasan) and products thereof		X		X		X		X
Milk and products thereof including lactose		X		X		X		X
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/litre expressed as SO ₂		X		X		X		X
Sesame seeds and products thereof		X		X		X		X
Celery and products thereof		X		X		X		X
Mustard and products thereof		X		X		X		X
Lupin and products thereof		X		X		X		X
Molluscs and products thereof		X		X		X		X