KRS Chemicals

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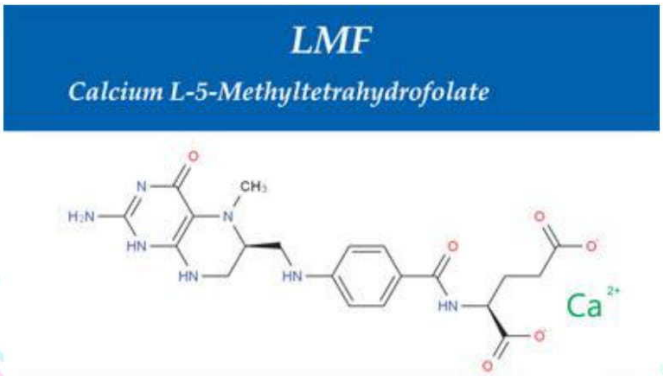
L-METHYLFOLATE Calcium



SYNONYMS

L-5-Methyltetrahydrofolic acid, calcium salt
L-Methyltetrahydrofolate, calcium salt
L-Methylfolate, calcium
L-5-MTHF-Ca

DEFINITION

Calcium L-5-methyltetrahydrofolate is the calcium salt of L-5-methyltetrahydrofolic acid, which is the predominant, naturally occurring form of folate. It is synthesized by reduction of folic acid to tetrahydrofolic acid followed by methylation and diastereoselective crystallization (in water) of L-5-methyltetrahydrofolic acid as its calcium salt. The product contains variable amounts of water of crystallization.

Chemical name

N-{4-[[((6S)-2-amino-3,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl)methyl]amino]benzoyl}-L-glutamic acid, calcium salt

$$\text{L-5-MTHF-Ca (\%)} = 100 \times A_T \times W_S \times S \times (100 - D) \times 1.083 / A_S \times W \times (100 - \%H_2O)$$

L Methylfolate calcium use

L-methylfolate is a medical food for use in people who have conditions related to folate deficiency. L-methylfolate is also used in people with major depressive disorder who have folate deficiency, or in people with schizophrenia who have hyperhomocysteinemia related to folate deficiency.

A lack (deficiency) of folate in the human body can be caused by certain diseases, by taking certain medications, or by not getting enough folate in your diet. Folate deficiency can lead to decreased red blood cells, or anemia. Folate deficiency can also cause high levels of a certain amino acid in the blood, a condition called hyperhomocysteinemia (HYE-per-HOE-moe-sis-tin-EE-mee-a).

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L-methylfolate is not an antidepressant or anti-psychotic medication. However, l-methylfolate may enhance the effects of antidepressant medications.

C.A.S. number	151533-22-1
Chemical formula	$C_{20}H_{23}CaN_7O_6$ (anhydrous form)
Formula weight	497.5 (anhydrous form)
Assay	95.0 - 102.0% (anhydrous basis)
DESCRIPTION	White to light yellowish, almost odourless, crystalline powder
FUNCTIONAL USES	Nutritional supplement
CHARACTERISTICS	
IDENTIFICATION	
Solubility	Sparingly soluble in water and very slightly soluble or insoluble in most organic solvents; soluble in alkaline solutions
Infrared absorption	The infrared absorption spectrum of a potassium bromide dispersion of the sample corresponds to that of a Calcium L-5-methyltetrahydrofolate standard (see Appendix).

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Calcium	Dilute 30 g of acetic acid (glacial) to 100 ml with water. Dissolve 5.3 g of K4Fe(CN)6 in 100 ml of water. To 5 ml of the acetic acid solution, add 20 mg of the sample and then 0.5 ml of the potassium ferrocyanide solution. Mix and add 50 mg of ammonium chloride. A white crystalline precipitate is formed.
Liquid chromatography	Retention time matches that of a reference standard (see under TESTS)

PURITY

Water	Not more than 17.0% (Karl Fischer method) Note: Allow sufficient time (15 min) for release of bound water.
Calcium	7.0 - 8.5% (anhydrous basis) Accurately weigh 500 mg of sample and transfer to a 500-ml conical flask. Add150 ml of water to dissolve the sample and 20 ml of a pH 10 buffer (NH3/NH4Cl). Using eriochrome black T as indicator, titrate (continuous stirring) with standardized 0.1 M EDTA until the colour changes from violet to blue/green. Each 1.0 ml of 0.1 M EDTA corresponds to 4.008 mg of calcium. Calculate the calcium content on the anhydrous basis.
Other folates and related substances	Not more than 2.5% See description under TESTS
D-5-Methylfolate	Not more than 1.0% See description under TESTS

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Total viable aerobic count	Not more than 1000 CFU/g
Lead	Not more than 2 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in FNP 5, "Instrumental methods".

Folic acid is the man-made form of folate. Folate is a B-vitamin naturally found in some foods. It is needed to form healthy cells, especially red blood cells.Folic acid supplements may come in different forms (such as L-methylfolate, levomefolate, methyltetrahydrofolate). They are used to treat or prevent low folate levels. Low folate levels can lead to certain types of anemia. Conditions that can cause low folate levels include poor diet, pregnancy, alcoholism, liver disease, certain stomach/intestinal problems, kidney dialysis, among others. Women of childbearing age should receive adequate amounts of folic acid either through their diet or supplements to prevent infant spinal cord birth defects.

Manufacturing Process

A solution of Folic acid in sodium hydroxide is reduced with Sodium borohydride to get tetrahydrofolate, which is reacted with formaldehyde and
reduced again with sodiumborohydride and then treated with

Calcium chloride to get Calcium methylfolate crude

Method of Asay	Calculate the percentage of L-5-MTHF-Ca in the sample from the content of 5-MTHF-Ca (L- and D-diastereoisomers), determined in the test for "Other folates and related substances", and the content of D-5-MTHF-Ca, determined in the test for D-5-Methylfolate, and correcting for water content, as follows: