Certificate of Analysis

Product Name	:	**(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE EP**
Description	:	PA/PE bag in PE/Alu bag, both vacuum sealed, in cardboard box
Product Code	:	510003-00-00
Lot	:	B00051
Manufacturing Date	:	25-APR-2017
Release Date	:	19-MAY-2017
Retest Date	:	15-APR-2019
Storage Conditions	:	Store at 2-8 °C under vacuum, protected from light.

Tests	Specifications			Unit of Measure	Results
	Target	Min	Max		
Appearance	White to yellowish powder				Conform
IR spectrum	Comparable to reference spectrum				Comparable
Test for calcium	Positive for calcium				Positive
Specific optical rotation (1.0% in THAM buffer, pH 8.1, 25 °C)		-15	-10	-	-13
10-formylfolic acid			0.8	%	0.11
p-aminobenzoylglutamic acid			0.8	%	< 0.05
5,10-diformyltetrahydrofolic acid			0.8	%	0.06
Folic acid			0.8	%	< 0.05
5-formyltetrahydropteroic acid			0.8	%	< 0.05
10-formyldihydrofolic acid			0.8	%	0.08
7,8-dihydrofolic acid			0.8	%	< 0.05
Any unspecified impurity (major)			0.10	%	0.08
Sum of related substances (excluding 10-formylfolic acid)			2.0	%	0.26
(6R)-folinic acid (impurity H)			0.5	%	< 0.3
Residual ethanol			3.0	%	0.4
Residual acetone			0.5	%	< 0.10
pH (0.8% in water)		7.5	8.5	-	7.9
Clarity (0.8% in water)	Clear solution				Clear
Absorbance (0.8% in water, 420 nm)			0.25	Au	0.03
Heavy metals			50	ppm	10
Water content (by Karl Fischer)		10.0	17.0	%	12.5
Chlorides	Not more than 0.5%				Conform
Total aerobic microbial count			500	cfu/g	0
Escherichia coli	Absent/g				Absent/g

Cerbios-Pharma SA
Via Figino 6
6917 Barbengo/Lugano
SWITZERLAND

Phone +41 (0)91 985 63 11
Telefax +41 (0)91 985 63 25
E-mail info@cerbios.ch
Web www.cerbios.ch

Product Name	:	**(6S)-CALCIUM FOLINATE / CALCIUM LEVOFOLINATE EP**
Description	:	PA/PE bag in PE/Alu bag, both vacuum sealed, in cardboard box
Product Code	:	510003-00-00
Lot	:	B00051

Tests	Specifications			Unit of Measure	Results
	Target	Min	Max		
Salmonella spp.	Absent/10 g				Absent/10 g
Staphylococcus aureus	Absent/g				Absent/g
Pseudomonas aeruginosa	Absent/g				Absent/g
Total molds and yeasts			100	cfu/g	0
Bacterial endotoxins (LAL test)			0.500	EU/mg	< 0.100
(6S)-calcium folinate (anhydrous and solvent free substance)		97.0	102.0	%	99.6
Calcium		7.54	8.14	%	7.89

Conformity Statement:

We herewith certify that this lot was manufactured, packaged and analysed by Cerbios-Pharma SA, CH-6917 Barbengo/Lugano, Switzerland, according to cGMP and to the current registration dossier by trained personnel; results were found to comply with the registered specifications.

No quality relevant deviations occurred during the lot manufacturing and quality control.

The manufacturing and analytical records have been reviewed and approved.

Based on the above, this lot is conform and released.

Note: With regard to platinum to be controlled according to the EP monograph for this drug substance, we state that the drug substance is manufactured without using platinum catalyst, and it is not tested for routinely, but that the drug substance would meet specification if it were tested for.

Barbengo, July 11, 2017

Cerbios-Pharma SA
Alessandro Perenna
QA Manager

Cerbios-Pharma SA
Via Figino 6
6917 Barbengo/Lugano
SWITZERLAND

Phone +41 (0)91 985 63 11
Telefax +41 (0)91 985 63 25
E-mail info@cerbios.ch
Web www.cerbios.ch