

CURESUPPORT NEDERLAND B.V. **ZUTPHENSEWEG 55, 7418 AH** DEVENTER, THE NETHERLANDS.

BIOAVAILABILITY STUDY OF VITAMIN C.

STUDY NO: CT-0007-17

THIS BIOAVAILABILITY STUDY IS PERFORMED BY BIO AGILE THERAPEUT.





BIOAVAILABILITY STUDY OF LIPOSOMAL VITAMIN C

OBJECTIVE OF THE STUDY

To evaluate the oral bioavailability of Liposomal Vitamin C 5ml/1000mg of CureSupport Nederland B.V. Zutphenseweg 55, Deventer and Non Liposomal Vitamin C 5ml/1000mg (Reference) Of CureSupport Nederland B.V. Zutphenseweg 55, Deventer. In healthy, adult, human subjects under fasting condition.

NUMBER OF SUBJECTS

Number of subjects planned: 24 Number of subjects completed the study and analyzed: 24

TESTED PRODUCT

Product name: Liposomal Vitamin C 5ml/1000mg

Manufactured by: CureSupport Nederland B.V. Zutphenseweg 55, 7418 AH, Deventer, The Netherlands.

Batch No: 171106

REFERENCE PRODUCT

Product name: Non Liposomal Vitamin C 5ml/1000mg

Manufactured by: CureSupport Nederland B.V. Zutphenseweg 55, 7418 AH, Deventer, The Netherlands.

Lot No: 171164

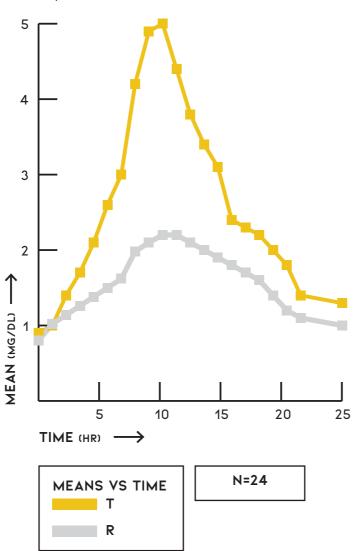
DOSE AND MODE OF ADMINISTRATION

A single oral dose, 5 ml of test product (T) or Reference product was administered by using syringe (as per randomization schedule) orally, after administration of Investigational Medicinal products, syringe was rinsed with 240 ml of drinking water, at ambient temperature, to the subjects in sitting posture under fasting condition. Treatment administration was separated by wash out period 7 days.

CONCLUSION

Based on the results obtained in this study, the test product (T).

Liposomal Vitamin C 5ml/1000mg of CureSupport Nederland B.V. Zutphenseweg 55, Deventer are found to be at least 1.7 times more bioavailable than published reports (on healthy, adult, human subjects under fasting conditions) of the competition.



RESULTS

GEOMETRIC MEAN OF REFERENCE PRODUCT (R) AND TEST PRODUCT (T)	
FOR ASCORBIC ACID (VITAMIN C)	

PHARMACOKINETIC PARAMETER	N	REFERENCE PRODUCT (R)	TEST PRODUCT (T)
C_{max} (mg/dL) AUC_{0-t} (mg*hr/dL) $AUC_{0-\infty}$ (mg*hr/dL) t_{max} (hr)	24 24 24 24	2.1695 31.5286 57.1165 3.42	5.2386 55.8627 78.9010 3.51
t _{max} (111) K _{el} (1/hr) t _{1/2} (hr)	24 24 24	0.0365 18.9995	0.0559 12.3895

STATISTICAL RESULTS OF TEST PRODUCT (T) VERSUS REFERENCE PRODUCT (R) FOR VITAMIN C

PHARMACOKINETIC PARAMETER	GEOMETRIC LEA	ST SQUARE MEAN	INTRA	T/R RATIO(%)
	TEST PRODUCT (T)	REFERENCE PRODUCT (R)	SUBJECT CV (%) (T VS. R)	
C _{max} (mg/dL)	5.2386 2.1695	5	8.19%	241.47%
AUC_{0-t} (mg*hr/dL)	55.8627 31.528	36	13.32%	177.18%
$AUC_{0-\infty}$ (mg*hr/dL)	78.9010 57.116	5	23.66%	138.14%

ORAL BIOAVAILABILITY VALUE FOR LIPOSOMAL VITAMIN C

PHARMACOKINETIC PARAMETER	TEST PRODUCT (MEAN ± STANDARD DEVIATION)	REFERENCE PRODUCT (MEAN ± STANDARD DEVIATION)	ORAL BIOAVAILABILITY VALUE (AUCO-T OF TEST / AUCO-T OF REFERENCE)
AUC _{0-t} (mg.hr/dL)	(56.3218 ± 7.3274)	(31.9704 ± 7.3274)	1.76

CMAX LEVELS OF LIPOSOMAL VITAMIN C VS NON-LIPOSOMAL VITAMIN C

Comparative Cmax Data of this Clinical Trials had shown that CureSupport Liposomal Vitamin C can increase the Bioavailability **6,6 times.**

