PRONORDIC®

MANUFACTURED AND PATENTED BY:
CURESUPPORT NEDERLAND B.V.
ZUTPHENSEWEG 55, 7418 AH
DEVENTER, THE NETHERLANDS.

MANUFACTURED FOR:
PHOENIX MEDCARE LTD,
AUCKLAND, NEW ZEALAND.

BIOAVAILABILITY STUDY
OF VITAMIN C.

STUDY NO: CT-0007-17

THIS BIOAVAILABILITY STUDY
IS PERFORMED BY BIO AGILE
THERAPEUT.

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STUDY NO: CT-0007-17

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

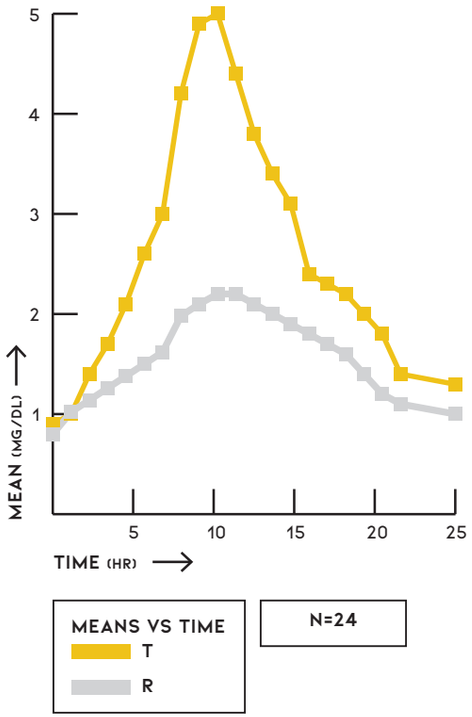
Manufactured by:
CureSupport Nederland B.V.
Zutphenseweg 55, 7418 AH,
Deventer, The Netherlands.

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 6.6 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)	24	2.1695	5.2386
AUC_{0-t} (mg*hr/dL)	24	31.5286	55.8627
$AUC_{0-\infty}$ (mg*hr/dL)	24	57.1165	78.9010
t_{max} (hr)	24	3.42	3.51
K_{el} (1/hr)	24	0.0365	0.0559
$t_{1/2}$ (hr)	24	18.9995	12.3895

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

PHARMACOKINETIC PARAMETER	GEOMETRIC LEAST SQUARE MEAN		INTRA SUBJECT CV (%) (T VS. R)	T/R RATIO(%)
	TEST PRODUCT (T)	REFERENCE PRODUCT (R)		
C_{max} (mg/dL)	5.2386	2.1695	8.19%	241.47%
AUC_{0-t} (mg*hr/dL)	55.8627	31.5286	13.32%	177.18%
$AUC_{0-\infty}$ (mg*hr/dL)	78.9010	57.1165	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 (AUC_{0-T} OF TEST / AUC_{0-T} OF REFERENCE)
AUC_{0-t} (mg.hr/dL)	(56.3218 ± 7.3274)	(31.9704 ± 7.3274)	1.76