



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

BIOAVAILABILITY STUDY OF
CUROSOME CURCUMINE.

STUDY NO: SLS-CT-0006-17

THIS BIOAVAILABILITY STUDY
IS PERFORMED BY BIO AGILE
THERAPEUT.



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STUDY OF

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CURESUPPORT
IT'S ALL ABOUT ABSORPTION

BIOAVAILABILITY STUDY OF LIPOSOMAL CUROSOME CURCUMIN

OBJECTIVE OF THE STUDY

To evaluate the blood concentration of Liposomal Curosome Curcumin 500 mg (250mg curcumin) per dosage of 25 ml of Curesupport Holding B.V. Zutphenseweg 55, Deventer and Non Liposomal Curcumin 500mg (250mg curcumin) per dosage of 25ml of Curesupport Holding B.V. Zutphenseweg 55, Deventer (Reference) in healthy, adult, human Subjects.

NUMBER OF SUBJECTS

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

TESTED PRODUCT

Product name:
Liposomal Curosome Curcumin 500 mg (250mg curcumin) per dosage of 25 ml

Manufactured by:
Curesupport Holding B.V.
Zutphenseweg 55, 7418 AH,
Deventer, The Netherlands.

Batch No: 171133

REFERENCE PRODUCT

Product name:
Non Liposomal Curcumin 500 mg (250 mg curcumin) per dosage of 25 ml

Manufactured by:
Curesupport Holding B.V.
Zutphenseweg 55, 7418 AH,
Deventer, The Netherlands.

Lot No: 17001909

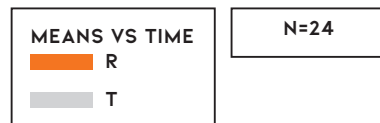
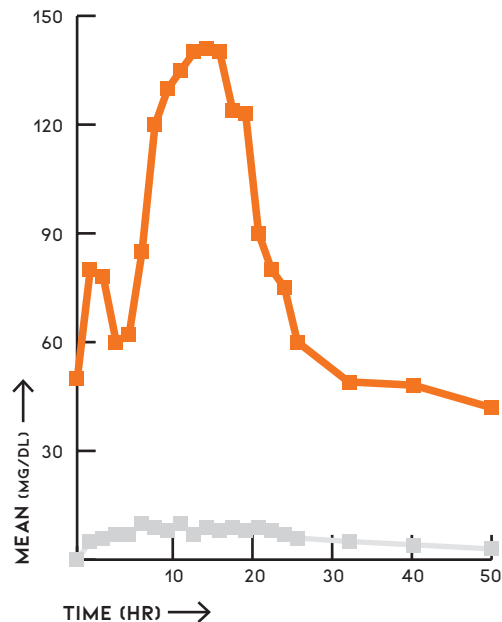
DOSE AND MODE OF ADMINISTRATION

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 5 days.

CONCLUSION

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

Liposomal Curosome Curcumin 500 mg (250mg curcumin) per dosage of 25 ml Of Curesupport Holding B.V. Zutphenseweg 55, Deventer are found to be 16.73 times more bioavailable than the reference product Non Liposomal Curcumin 500 mg (250 mg curcumin) per dosage of 25 ml of Curesupport Holding B.V. Zutphenseweg 55, Deventer. In healthy, adult, human subjects under fasting conditions.



RESULTS

GEOMETRIC MEAN OF REFERENCE PRODUCT (R) AND TEST PRODUCT (T) FOR CURCUMIN

PHARMACOKINETIC PARAMETER	N	REFERENCE PRODUCT (R)	TEST PRODUCT (T)
C _{max} (ng/mL)	24	13.6340	184.9859
AUC _{0-t} (ng*hr/mL)	24	147.3168	2088.5252
AUC _{0-∞} (ng*hr/mL)	24	172.6414	3294.4899
t _{max} (hr)	24	3.52	4.45
K _{el} (1/hr)	24	0.0495	0.0191
t _{1/2} (hr)	24	13.9944	36.3093

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

PHARMACOKINETIC PARAMETER	GEOMETRIC LEAST SQUARE MEAN		INTRA SUBJECT CV (%) (T VS. R)	T/R RATIO(%)
	REFERENCE PRODUCT (R)	REFERENCE PRODUCT (R)		
C _{max} (ng/mL)	184.9859	13.6340	43.41%	1356.80%
AUC _{0-t} (ng*hr/mL)	2088.5252	147.3168	55.68%	1417.71%
AUC _{0-∞} (ng*hr/mL)	3294.4899	172.6414	61.34%	1908.28%

ORAL BIOAVAILABILITY VALUE FOR LIPOSOMAL CURCUMIN

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} (ng.hr/mL)	(3038.4973 ± 2324.9523)	(181.5162 ± 106.4195)	16.73