

CURESUPPORT NEDERLAND 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.





# 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 Nederland B.V. Zutphenseweg 55, Deventer and Non Liposomal Curcumin 500mg (250mg curcumin) per dosage of 25ml of CureSupport Nederland 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 Nederland 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 Nederland B.V. Zutphenseweg 55, 7418 AH, Deventer. The Netherlands.

Lot No: 17001909

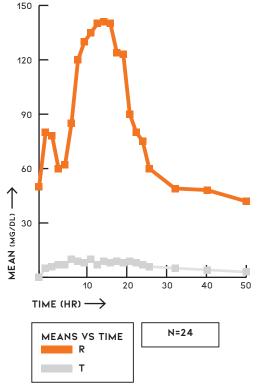
#### DOSE AND MODE OF ADMINISTRATION

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 Nederland 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 Nederland 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 FOR CURCUMIN					
PHARMACOKINETIC PARAMETER	N	REFERENCE PRODUCT (R)	TEST PRODUCT (T)		
C <sub>max</sub> (ng/mL)	24	1 3.6340	184.9859		
AUC <sub>0-t</sub> (ng*hr/mL)	24	147.3168	2088.5252		
AUC₀-∞ (ng*hr/mL)	24	172.6414	3294.4899		
t <sub>max</sub> (hr)	24	3 .52	4.45		
K <sub>el</sub> (1/hr)	24	0 .0495	0 .0191		
t <sub>1/2</sub> (hr)	24	13.9944	36.3093		

STATISTICAL RESULTS OF TEST PRODUCT (T) VERSUS REFERENCE PRODUCT (R) FOR CURCUMIN							
PHARMACOKINETIC PARAMETER	GEOMETRIC LEAS	T SQUARE MEAN	INTRA SUBJECT CV (%) (T VS. R)	T/R RATIO(%)			
	REFERENCE PRODUCT (R)	REFERENCE PRODUCT (R)					
$C_{max}$ (ng/mL) AUC <sub>0-t</sub> (ng*hr/mL) AUC <sub>0-<math>\infty</math></sub> (ng*hr/mL)	184.9859 2088.5252 3294.4899	13.6340 147.3168 172.6414	43.41% 55.68% 61.34%	1356.80% 1417.71% 1908.28%			

ORAL BIOAVAILABILITY VALUE FOR LIPOSOMAL CURCUMIN						
PHARMACOKINETIC PARAMETER	TEST PRODUCT (MEAN ± STANDARD DEVIATION)	REFERENCE PRODUCT (MEAN ± STANDARD DEVIATION)	ORAL BIOAVAILABILITY VALUE (AUCo-+ OF TEST / AUCo-+ OF REFERENCE)			
AUC <sub>0-t</sub> (ng.hr/mL)	(3038.4973 ± 2324.9523)	(181.5162 ± 106.4195)	16.73			

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