

Objective of the Study

To evaluate the blood concentration of Liposomal Cureit® Curcumin 500 mg per dosage of 25 ml of Curesupport B.V. Zutphenseweg 55, Deventer and Non Liposomal Curcumin 500mg per dosage of 25ml of Curesupport 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 Cureit® Curcumin 500 mg per dosage of 25 ml

Manufactured by:
Curesupport B.V.
Zutphenseweg 55, Deventer.

Batch No : 171133

Reference product

Product name:
Non Liposomal Curcumin 500 mg per dosage of 25 ml

Manufactured by:
Curesupport B.V. Zutphenseweg 55, Deventer.

Lot No: 17001909

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
$AUC_{0-\infty}$ (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 3	6.3093

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 (%)
	Test Product (T)	Reference Product (R)		
C_{max} (ng/mL)	184.9859 1	13.6340 4	3.41%	1356.80%
AUC_{0-t} (ng*hr/mL)	2088.5252	147.3168 5	5.68%	1417.71%
$AUC_{0-\infty}$ (ng*hr/mL)	3294.4899	172.6414 6	1.34%	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

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

