

lipolife[®]

BIOAVAILABILITY STUDY LIPOLIFE[®] TURMEREASE

This bioavailability study was performed by Bio Agile Therapeut
Study No: SLS-CT-0006-17

Objective of the Study

To evaluate the blood concentration of Curcumin in healthy, adult test subjects using Lipolife[®] Turmerease Cureit[®] Curcumin at 500 mg per 25ml against Non-Liposomal Curcumin at 500mg per 25ml.

Number of Test Subjects

24 planned
24 completed
24 analysed

Test Product (T)

Lipolife[®] Turmerease Cureit[®] Curcumin
25ml dose = 500mg Curcumin
Batch ID 171133

Reference Product (R)

CureSupport Non-Liposomal Curcumin
25 ml dose = 500mg Curcumin
Batch ID 17001909

Dosage and Administration

A single 5ml oral dose of test product (T) or reference product (R) was administered by using a syringe (as per randomisation schedule).

Following the administration of the test or reference product, the syringe was rinsed with 240ml of ambient temperature drinking water to collect any residue and given to the test subjects whilst in sitting posture and under fasted conditions.

Treatment administration for (T) and (R) was separated by a 5 day period.

Geometric Mean of Reference product (R) and Test product (T) for Curcumin

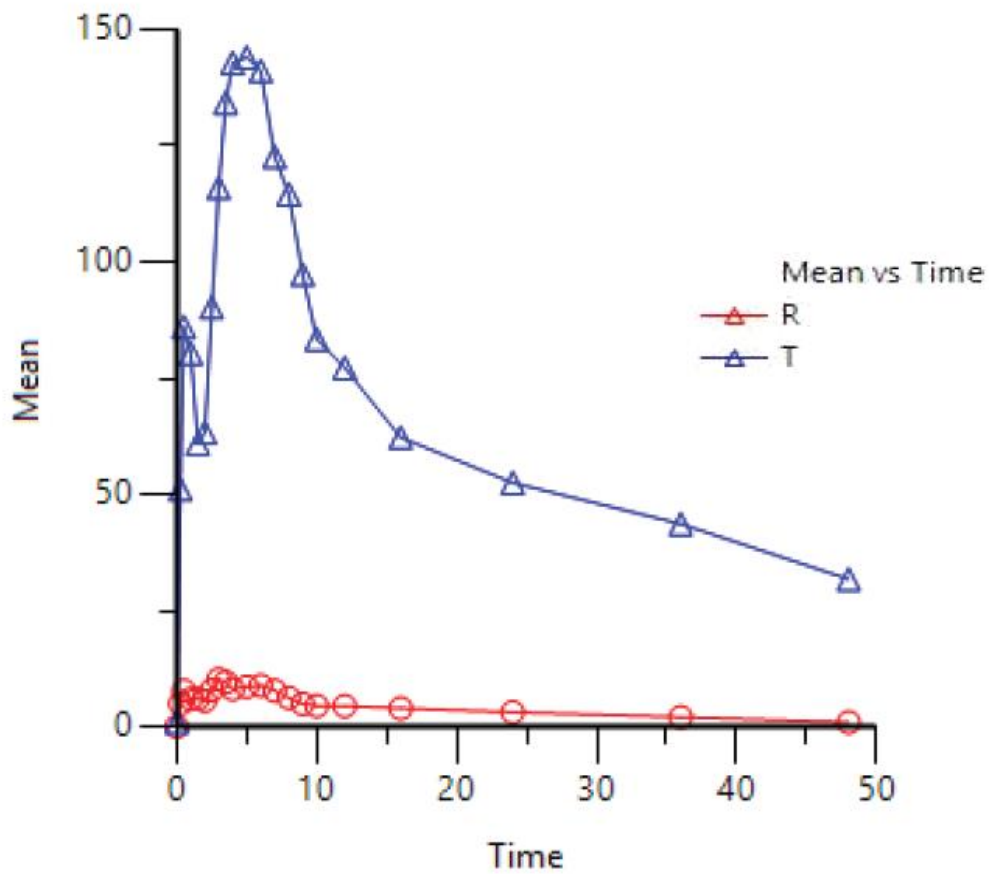
Pharmacokinetic Parameter	N	Reference Product (R)	Test Product (T)
C_{max} (ng/mL)	24	13.6340	184.9859
AUC_{0-t} (ng*hr/mL)	24	147.3168	2088.5252
$AUC_{0-\infty}$ (ng*hr/mL)	24	172.6414	3294.4899
t_{max} (hr)	24	3.52	4.45
K_{el} (1/hr)	24	0.0495 0	.0191
$t_{1/2}$ (hr)	24	13.9944 3	6.3093

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 \pm Standard Deviation)	Reference Product (Mean \pm Standard Deviation)	Oral bioavailability value (AUC_{0-t} of Test / AUC_{0-t} of Reference)
AUC_{0-t} (ng.hr/mL)	(3038.4973 \pm 2324.9523)	(181.5162 \pm 106.4195)	16.73



Conclusion

Based on the results obtained in this study, the test product (T) Lipolife® Turmerase Cureit® Curcumin has been found to be 16.73 times more bioavailable than the reference product (R) CureSupport Non-Liposomal Curcumin.

