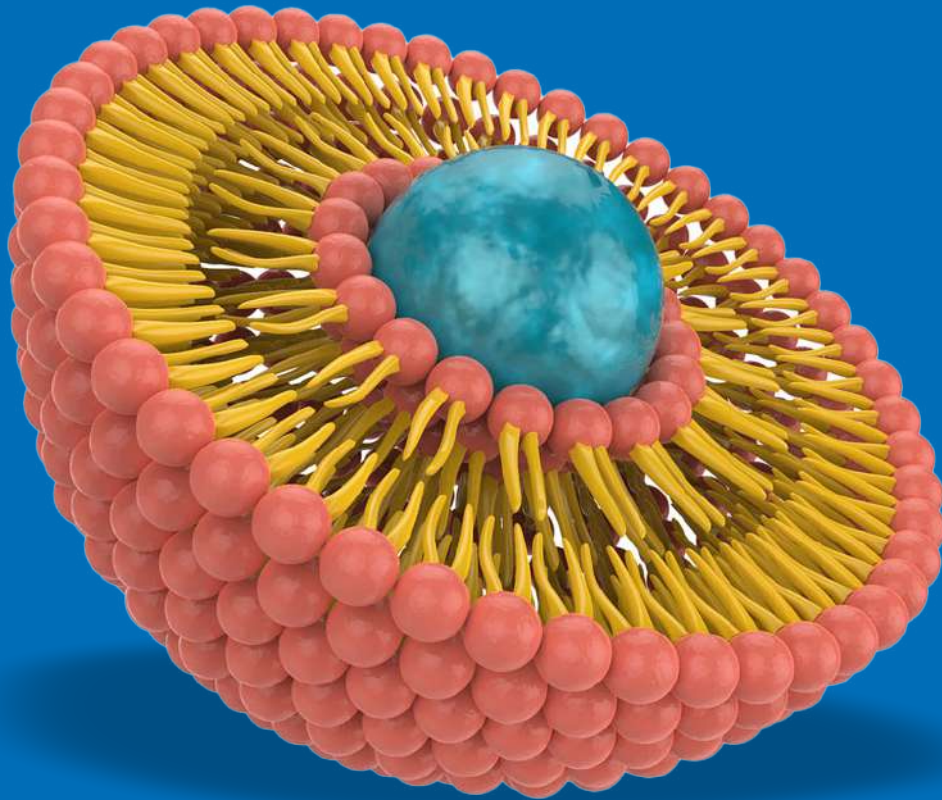




Liposomal Vitamin C

**EVALUATING THE CLINICAL IMPACT
OF LIPOMAC[™]: INSIGHTS INTO
BIOAVAILABILITY**



Botanic Healthcare Pvt. Ltd.

Hyderabad, Telangana - 500076, INDIA

USA | Germany | Australia | New Zealand



LipsoBio[®]

www.lipsobio.com

Objective:

- To assess the bioavailability of Lipomac – Liposomal Vitamin C and non-liposomal Vitamin-C formulations in healthy, adult, human volunteers.

Subjects:

- Number of Subjects planned: 12
- Number of Subjects completed the study: 12

Test product information:

- Lipomac (Liposomal Vit C): 500mg (2 capsules at a time)

Reference product information:

- Non-Liposomal Vit C: 500mg (2 capsules at a time)

Manufactured by:

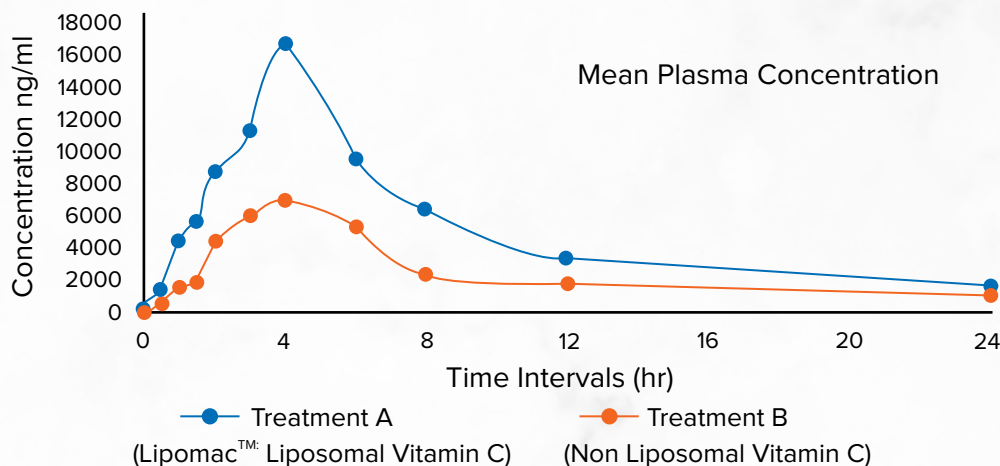
- Botanic Healthcare Pvt Ltd; India

Dose and mode of administration:

- After overnight fasting for at least 10 hours, 500mg (2 capsules at a time) of both the study products will be administered orally to each subject in sitting posture, with about 240 mL of water at ambient temperature, as a single dose, in study period, as per the randomization code list. A washout period of 5 days from day 0 was maintained.

Results:

- This study evaluated the safety and pharmacokinetic parameters for bioavailability of Liposomal Vitamin C formulation. From the study it concluded that the Lipomac™ (Liposomal Vitamin C) formulation has better superior bioavailability (C max and AUC) compared to the non-liposomal Vitamin C preparation. The study also concludes that Lipomac™ (Liposomal Vitamin C) is better bioavailable by 2.36 folds over the non-liposomal Vitamin C formulation.



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

Pharmacokinetic Parameter	N	Reference Product (R)	Test Product (T)
C _{max} (mg/dL)	12	6934.21	16461.20
AUC _{0-t} (mg*hr/dL)	12	60382.88	12291.12
AUC _{0-∞} (mg*hr/dL)	12	74364.01	139236.10
t _{max} (hr)	12	4	4
K _{el} (1/hr)	12	0.081	0.103
t _{1/2} (hr)	12	8.31	6.80

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)	16111.20	6387.15	1.497 Vs 7.32	252.24%
AUC _{0-t} (mg*hr/dL)	113601.10	53897.10	4.38 Vs 6.70	210.77%
AUC _{0-∞} (mg*hr/dL)	127006.32	62793.13	4.44 Vs 9.15	202.26%

Oral bioavailability value for Liposomal Vitamin C

Pharmacokinetic Parameter	Test Product (Mean ± Standard Deviation)	Reference Product (Mean ± Standard Deviation)	Oral bioavailability value (AUC0-t of Test / AUC0-t of Reference)
AUC0-t (mg.hr/dL)	122399.15 ± 5366.56	60506.06 ± 4058.56	2.0229



Get in touch with us

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