

BIOAVAILABILITY Study OF LIPOSOMAL Vitamin D

Objective of the Study

To evaluate the oral bioavailability of Liposomal Vitamin D 5ml/1000mg of Borealis Pharma B.V. Boeingavenue 8, Schiphol-Rijk and Non Liposomal Vitamin D 5ml/1000mg (Reference) Of Borealis Pharma B.V. Boeingavenue 8, Schiphol-Rijk. In healthy, adult, human subjects under fasting condition.

Number of subjects

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

Tested product

Product name:
Liposomal Vitamin D 5ml/ 1000mg

Manufactured for:
Borealis Pharma B.V. Boeingavenue 8, 1119 PB, Schiphol-Rijk, The Netherlands.

Batch No: 171106

Reference product

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

Manufactured for:
Borealis Pharma B.V. Boeingavenue 8, 1119 PB, Schiphol-Rijk, The Netherlands.

Lot No: 171164

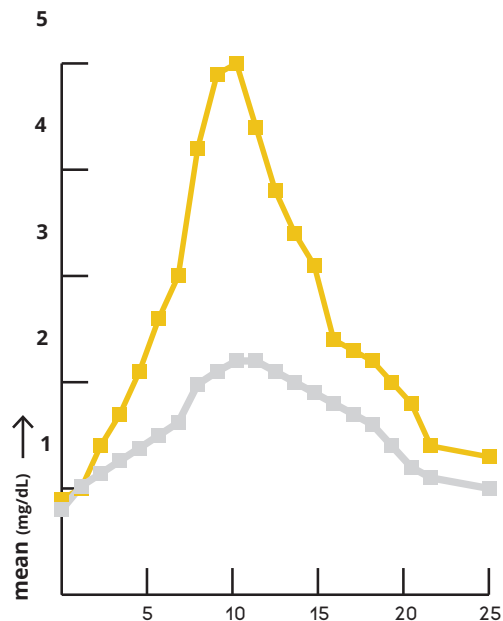
Dose and mode of administration

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 7 days.

Conclusion

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

Liposomal Vitamin D 5ml/1000mg of Borealis Pharma B.V. are found to be at least 6.6 times more bioavailable than published reports (on healthy, adult, human subjects under fasting conditions) of the competition.



Time (hr) →

Means vs time

■ R

■ T

n=24

Results

Geometric Mean of Reference product (R) and Test product (T) for Ascorbic acid (Vitamin C)

| Pharmacokinetic Parameter | N | reference Product (R) | Test Product (T) |
|-----------------------------|----|-----------------------|------------------|
| C_{max} (mg/dL) | 24 | 2.1695 | 5.2386 |
| AUC_{0-t} (mg*hr/dL) | 24 | 31.5286 | 55.8627 |
| $AUC_{0-\infty}$ (mg*hr/dL) | 24 | 57.1165 | 78.9010 |
| t_{max} (hr) | 24 | 3.42 | 3.51 |
| K_{el} (1/hr) | 24 | 0.0365 | 0.0559 |
| $t_{1/2}$ (hr) | 24 | 18.9995 | 12.3895 |

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) | 5.2386 | 2.1695 | 8.19% | 241.47% |
| AUC_{0-t} (mg*hr/dL) | 55.8627 | 31.5286 | 13.32% | 177.18% |
| $AUC_{0-\infty}$ (mg*hr/dL) | 78.9010 | 57.1165 | 23.66% | 138.14% |

Oral bioavailability value for Liposomal Vitamin D

| 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} (mg.hr/dL) | (56.3218 ± 7.3274) | (31.9704 ± 7.3274) | 1.76 |

