Stability report on Liposomal VITAMIN C

LOT 10534
SHELF LIFE: 12 MONTHS

The shelf-life of the product above mentioned has been determined with a Long-Term Testing. The storage time is at, or over, the intended shelf life. At the end of the stability testing, the data collected are satisfying and comparable to the features of the fresh product. The results suggest that the shelf life of this product can be established at 12 months, except if external influences, including storage and microbiological contamination, corrupt the stability.

The product was stored:

- in food-grade dark container;
- sealed on the day of production under controlled atmosphere;
- at temperatures between +10 C - +20 C;
- not exposed to direct sunlight;
- at average moisture of the storage of 35 - 50 %.

Analytic – Results show the product retains all analytical target features throughout shelf life

Parameter	Target	Result fresh product	Result at end of shelf life	Method
pH	4.0 – 5.5	4.8 (± 7 %)	5.00 (± 7 %)	PH-meter
Sp. Density	1.000 – 1.200	1.132	1.140	Aerometer [g/cm3]
Rel. Density	10 – 50	42	40	Refractometer [Brix%]
Viscosity	15 - 200	40	46	Viscometer [mPa s]

Organoleptic – Results show the product retains all sensory target features throughout shelf life

Parameter	Target	Result fresh product	Result at end of shelf life	Method
Appearance	Liquid	Complies	Complies	Optical
Colour	Beige / Yellow	Complies	Complies	Optical
Odour	Natural lecithin + Flavor	Complies - Orange	Complies - Faint	Sensorial
Taste	Natural lecithin taste	Complies	Complies	Sensorial
Texture	Homogeneous	Complies	Complies	Sensorial

Microbiology – Results show the product retains all microbiological target features throughout shelf life

Parameter	Target	Result fresh product	Result at end of shelf life	Method
TPC aerob	< 1000	< 10	0 colonies found	EU 2073/2005
TPC anaerob	< 1000	< 10	-	EU 2073/2005
Yeast & Mould	< 100	< 10	< 100	EU 2073/2005

Active ingredient stability – Complies with Regulation (EU) No 1169/2011

Expected depletion of ascorbic acid at end of shelf time[+] -12 %

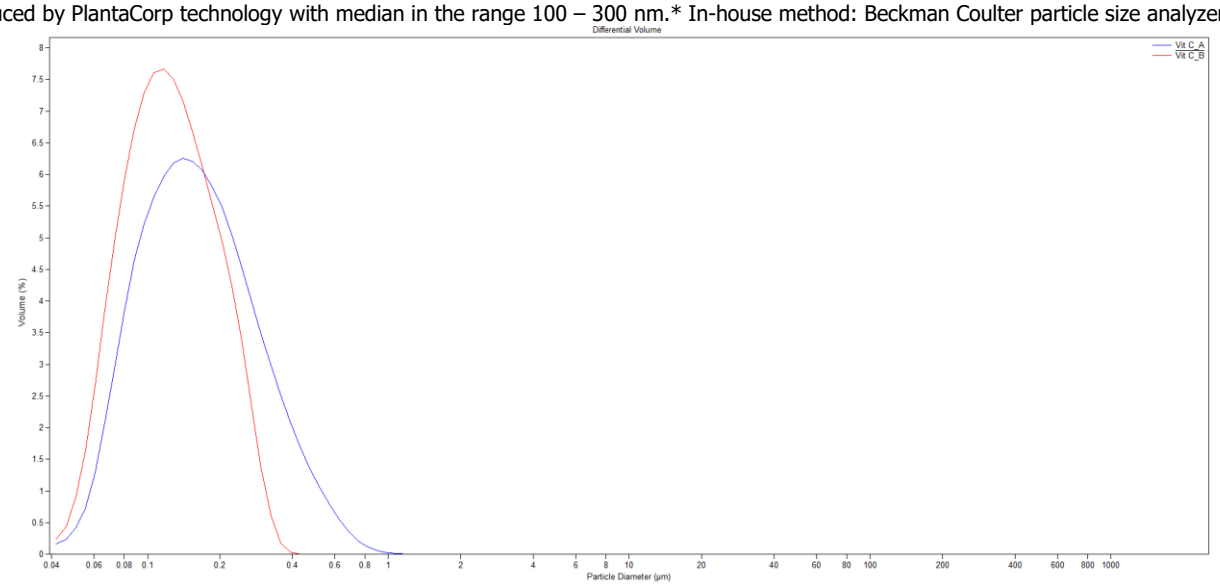
Recommended analytical method [a, b] PB-135/HPLC ed. II of 15.09.2015

[+] Depletion of active ingredient calculated from the value measured in fresh products and in product at the end of shelf life. Examples are: amount of ascorbic acid used at production 10000mg/100ml, measured in fresh product (9890 ± 700) mg/100ml, measured in product at the end of the shelf life (9670 ± 700) mg/100ml.
[a] Encapsulated active ingredient can be hindered from common analytical techniques. PlantaCorp is collaborating with Hamburg University of Applied Science to create new and efficient technologies to pre-treat the samples before analytical testing, to break the liposomes and release the entire amount of active ingredient for optimal measurements. Different analytical methods can provide different results. Some methods tested could not detect the full amount, a systematic error occurs on the measurement and a big uncertainty applies. Methods investigated on fresh and old products: PB-135/HPLC ed. II of 15.09.2015 and OP M 547:2016-08, HPLC.

[b] Depletion of active ingredient complies with Regulation (EU) No 1169/2011 on tolerances for nutrient values: Vitamins +50% and -20%.

Size analysis – Liposomal size distribution stable over time

The particle size distribution of liposomes encapsulating active ingredients provides a qualitative measurement of the stability of liposomes over time. The investigation of fraction of volume in function of particle size [µm] reveals that: i) there is one single population of particles (liposome), ii) stable over time (A fresh product, B product at end of shelf life), iii) with a size distribution known to be typical for the liposomes produced by PlantaCorp technology with median in the range 100 – 300 nm.* In-house method: Beckman Coulter particle size analyzer.



* Size distribution complies with https://www.efsa.europa.eu/en/topics/topic/nanotechnology as more than 50% of the particles external dimesnions is in the size range > 100nm.

Packaging

Bottles B01 250ml Brown Glass **Cups** C02 Rical