

TECHNICAL DATA SHEET

A009139-TDS-ENG-2019

PERLAS ACEITE ONAGRA					
DESCRIPTION DCI:		DESCRIPTION DOE:			
CAS Nº:	EC Nº:		AEMPS CODE:		
MOL. WEIGHT:	MOL. FORMULA::		ARTICLE CODE: A009139		

ATTRIBUTES SHOULD BE

Formula

Evening primrose oil 10% GLA

Natural Vitamin E 67 %

Complies manufacturer specifications

Vitaheess

Complies manufacturer specifications

Glycerin

Complies manufacturer specifications

Complies manufacturer specifications

Complies manufacturer specifications

Physico-chemical specifications

Size and shape 10 min. oval softgel Colour AP00_01 Natural

Average capsule $721.0 \pm 15 \% (612.9 - 829.2 \text{ mg})$

Average content (18/20) 505.1 mg \pm 7.5 % (467.2 - 543.0 mg) 80 % =< 30 μ m (20/20) 505.1 mg \pm 15 % (429.3 - 580.9 mg)

Thickness of the join => 50 %Disintegration test =< 30 min

Microbiological control

TAMC =< 10000 CFU/g

TYMC =< 100 CFU/g

Enterobacteria =< 100 CFU/g

Escherichia coli Absence/1g

Salmonella Absence/10g

Staphylococcus aureus Absence/1g

Listeria monocytogenes Absence/25g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool and dry place. Between 15 and 25 $^{\circ}\text{C}$ and below HR 60 %.

REMARKS

All data adapted from the manufacturer certificate of analysis.

Heavy metals

 $Plumb \le 3.0 ppm$ $Cadmium \le 1.0 ppm$ $Mercury \le 0.1 ppm$

According to Regulation (EC) N° 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.



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Metapharmaceutical Industrial either HC Clover does not perform any control of heavy metals by batch manufactured. These controls are required of our suppliers of raw materials.

Allergens

The gelatin used in the manufacture of the product contains Sulphites in quantities not exceeding 10 ppm. The product does not contain allergens indicated in the attachment II of the Regulation (UE) No 1169/2011.

GMO

This product is non OGM.

BSE-TSE

This product is BSE&TSE free.