



CERTIFICATO DI ANALISI N. F85274
CERTIFICATE OF ANALYSIS N.

Data 30.08.2018
 Date

Prodotto DALMAVITAL
Product Emulsion for injection - 100 ml
 Order no. FO 8355

Prep. N. 810166
 Batch No.
 Quantity: 700 vials

Determinazioni eseguite Analyses performed	Risultati delle analisi Results
<u>Appearance:</u> Clear or slightly opalescent, red-dark emulsion	Complies
<u>pH:</u> 5.5 – 7.0	6.2
<u>Composition:</u> Each ml contains	% of declared value
Active substances:	
- β -Carotene 15 mg	99.9
dl- α -Tocopheryl acetate 20 mg	101.0
(equivalent to dl- α -Tocopherol 18.22 mg)	
Excipients:	
- Chlorocresol 1 mg	99.5
- Butylhydroxyanisol 2.7 mg	100.1
Other excipients q.s. to 1 ml	
<u>Bacterial endotoxins</u> not more than 71 UI/ml	Complies
<u>Sterility</u> Sterile	Sterile
Osservazioni: Notes:	

Data di prep.: AUGUST 2018
 Mfg. date:

Data di scadenza: JULY 2020
 Exp. date:

Giudizio: APPROVED
 Comment:

SERVIZIO CONTROLLO QUALITÀ
 QUALITY CONTROL DEPARTMENT