



CERTIFICATO DI ANALISI N.
CERTIFICATE OF ANALYSIS N.

F53519

11.06.2015

Prodotto DALMAVITAL
Product Injectable solution - 100 ml
 Order no. F 5177

Data
Date
Prep. N.
Batch N 506826
Quantity: 1 655 vials

Determinazioni eseguite
 Analyses performed

Risultati delle analisi
 Results

Appearance: Clear or slightly opalescent,
 red-dark solution

Complies

pH: 5.50 – 7.00

6.28

Composition: Each ml contains

% of declared value

Active substances:

- β -Carotene 15.00 mg
 dl- α -Tocopherol acetate 20.00 mg
 (equivalent to dl- α -Tocopherol 18.22 mg)

100.6
 101.4

Excipients:

- Chlorocresol 1.00 mg
 - Butylhydroxyanisol 2.70 mg
 Other excipients q.s. to 1.00 ml

100.9
 101.5

Bacterial endotoxins not more than 71 UI/ml

Complies

Sterility Sterile product

Sterile

Osservazioni:
 Notes:

Data di prep.: MAY 2015
 Mfg. date:

Data di scadenza: APRIL 2017
 Exp. date:

Giudizio:
 Comment: APPROVED


 SERVIZIO CONTROLLO QUALITÀ
 QUALITY CONTROL DEPARTMENT