

Analizni izvid / Certificate of analysis

Int-rac- α -Tocopherylis acetat

Serijska številka / Batch n°: LX0072-120011 ✓
 Deklaracija / Corresponds to: Ph.Eur., USP, FCC
 Proizvajalec / Manufacturer: DSM Nutritional Products Ltd.

Datum analize / Date of analysis: 06/07/2012
 Datum proizvodnje / Manufacturing date: 04/2012
 Uporabno do / Expiry date: 04/2015 ✓

	Specifikacija / Specification Values	Rezultati / Batch Values
Lastnosti / Properties:	Bistra, brezbarvna ali rahlo zeleno-rumena viskozna, oljnata tekočina, skoraj netopna v vodi, lahko topna v acetonu, brezvodnem etanolu in maščobnih oljih. / Clear, colourless or slightly greenish-yellow, viscous, oily liquid, practically insoluble in water, freely soluble in acetone, in anhydrous ethanol and in fatty oils.	Ustreza / Conforms
Istovetnost / Identification:	v skladu s preskusom / it complies with the test	Ustreza / Conforms
Vsebnost / Assay (Ph.Eur.):	96,5 – 102,0 %	98,4
Vsebnost / Assay (USP/FCC):	96,0 – 102,0 %	99,1
Optični zasuk / Optical rotation:	-0,01° / +0,01°	-0,00
Težke kovine / Heavy metals:	≤ 10 ppm	Ustreza / Conforms
Svinec / Lead:	≤ 2 ppm	Ustreza / Conforms
Arzen / Arsenic:	≤ 1 ppm	Ustreza / Conforms
Živo srebro / Mercury:	≤ 0,1 ppm	Ustreza / Conforms
Kadmij / Cadmium:	≤ 0,5 ppm	Ustreza / Conforms
Zaostala topila / Residual solvents:		
. pyridine	≤ 200 ppm	Ustreza / Conforms
. toluene	≤ 890 ppm	Ustreza / Conforms
Kislota / Acidity:	≤ 1,0 ml 0,10N NaOH	0,0
Sorodne snovi / Related substances:		
. impurities A, C	≤ 0,5 %	0,1
. impurity B	≤ 1,5 %	0,6
. sum of impurities D and E	≤ 1,0 %	0,4
. any other impurity	≤ 0,25 %	0,11
. total	≤ 2,5 %	1,4

PHARMADENT d.o.o.
 Minarikova ul. 6
 2000 Maribor
 Prejel: FUJS DRAGO
 22.1.13
 Datum prejema: 16.1.13
 Pregledal: MARGOLT Robert mag. farm., spec.
 Datum pregleda: 17.1.2013

Opombe / Notes:

Mnenje / Opinion:

Po navedbah proizvajalca substanca ustreza zgoraj navedenim parametrom Ph.Eur.7, FCC, USP.
 According to the manufacturers specifications the substance corresponds to the stated parameters Ph.Eur.7, FCC, USP.

Ines LOGAR mag.farm., spec.

Vodja službe za zagotavljanje kakovosti
 Quality assurance manager

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Obr.: 7512

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Lex d.o.o. • Vanganeljska c. 26 • SI-6000 Koper
 tel.: +386 5 625 18 10 • fax: +386 5 625 18 12
 www.lex.si • www.lexarna.si