



KEMIG

Proizvodnja i prodaja farmaceutskih i kozmetičkih sirovina, ambalaže i gotovih proizvoda



GLYCEROLUM/Glicerol

INCI:	GLYCERIN
Kontrolni broj/Control number:	1701017
Zahtjev kvalitete/Quality request:	Ph.Eur. 9.0
Serijski broj/Batch:	00010716
Datum proizvodnje/Production date:	28.03.2017.
Datum retesta/Recertification date:	31.03.2019.
CAS:	56-81-5
Zemlja podrijetla/Country of origin:	Germany

ANALITIČKO IZVJEŠĆE/CERTIFICATE OF ANALYSIS

ISPITIVANJE/TEST	ZAHTJEV/REQUIREMENT	REZULTAT/RESULTS
Osobine/Characters	bistra, bezbojna ili gotovo bezbojna sirupasta tekućina, masna opipa, miješa se s vodom i alkoholom, teško topiv u acetonu, gotovo netopiv u masnim i biljnim uljima/syrupy liquid, unctuous to the touch, colorless or almost colorless, clear, very hygroscopic, miscible with water and with alcohol, slightly soluble in acetone, practically insoluble in fatty oils and in essential oils	odgovara/conform
Identifikacija/Identification:	A; C; D	odgovara/conform
Izgled otopine/Appearance of solution	bistra i bezbojna/clear and colorless	odgovara/conform
Kiselost ili lužnatost/Acidity or alkalinity	odgovara testu/correspond to test	odgovara/conform
Indeks refrakcije/Refractive index	1,470 – 1,475	1,4734
Aldehidi/Aldehydes	≤ 10 ppm	< 10 ppm
Esteri/Esters	0,1 M HCl > 8 ml	8,96 ml
Onečišćenje A i srodne tvari/ Impurity A and related substance (GC):		
A; Diethylen glycerol:	≤ 0,1 %	< 0,1 %
Pojedinačna; Rt<glicerol/ Any other impurity Rt<glycerol	≤ 0,1 %	0,03 %
Ukupna; Rt>glicerol/ Total of all impurities Rt>glycerol	≤ 0,5 %	< 0,5 %
Halogeni spojevi/Halogenated compounds	≤ 35 ppm	< 35 ppm
Šećeri/Sugars	odgovara testu/correspond to test	odgovara/conform
Kloridi/Chlorides	≤ 10 ppm	< 5 ppm
Teški metali/Heavy metals	≤ 5 ppm	< 5ppm
Voda/Water	≤ 2,0 %	0,05 %
Sulfatni pepeo/Sulphated ash	≤ 0,01 %	< 0,01 %
Sadržaj/Assay	98,0 % - 101,0 %	99,95 %

Mišljenje/Opinion: Prema ispitanim parametrima uzorak odgovara Ph.Eur 9.0
According to the tested parameters the sample corresponds to Ph.Eur.9.0

Analiza izvršen/Date of analysis: 05.04.2017.
Analitičar/Analyst: GK

Voditelj kontrolno analitičkog laboratorija /Responsible quality control laboratory manager
mr.ph.Elizabeta Marok-Grilec mr.sc.
Specijalista ispitivanja i kontrole lijekova /Medicals control and testing specialist

222

Donjozelinska 114 · 10382 Donja Zelina · Tel.: +385 1 2043322 · Faks: +385 1 2043220 · e-mail: kemig@kemig.hr · www.kemig.hr
OIB:10383719392 · IBAN: HR5524020061100604591