

s.p. química, s.a.

DONORJUE:
C/ra. Plaça-Vinyola, km 4.1
Tel. (34) 977 85 00 20
Teletax (34) 977 85 05 21
43350 - RIUDOMS (Tarragona)

COORDINADORA:
Aparador / P.O. Box 78
43350 - RIUDOMS (Tarragona) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 14 JANUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.9 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.21 %	SPA-1007-04
Water (KF):	≤0.5%	0.14 %	SPA-1007-04
Formaldehyde:	≤200 ppm	145 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.7	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA
0.02 % PROPYL GALLATE
0.01 % THIODIPROPIONIC ACID

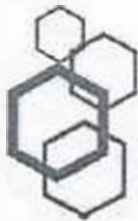
Specifications according to European Pharmacopoeia.
The product is manufactured from 100% vegetable glycerine origin.
The glycerine contains no detectable traces of GMOs.
The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents listed by ICH and inserted in the European Pharmacopoeia.

Handwritten signature and stamp: "Eva Rosa Vinyola Km. 4.1 43350 RIUDOMS (Tarragona)"

Manufacture Date: JANUARY 2016
Expiry Date: JANUARY 2019

SP QUÍMICA, S.A.
Quality Control

MP.CC.009_3. ANEXO 7
COD.SPE-1007-03



s.p. química, s.a.

DOMICILIO:
C/la. Fáb. Vinyola, km 4,1
Tel. (34) 977 85 00 26
Telefax (34) 977 85 05 21
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 78
43330 - RIUDOMS (Tarragona) SPAIN
E-mail: spquímica@spquímica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 19 JANUARY 2016

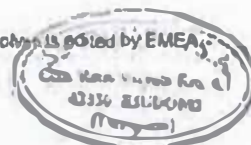
CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (98 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.7 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.30 %	SPA-1007-04
Water (KF):	≤0.5%	0.15 %	SPA-1007-04
Formaldehyde:	≤200 ppm	123 ppm	SPA-1007-04
Peroxides:	≤15 ppm	<1 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.5	SPA-1007-04
Relative density:	1.210-1.220	1.217	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA
0.02 % PROPYL GALLATE
0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopoeia.
The product is manufactured from 100% vegetable glycerine origin.
The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvent and inserted in the European Pharmacopoeia.



Manufacture Date: JANUARY 2016
Expiry Date: JANUARY 2019

SP QUÍMICA, S.A.
Quality Control!

MP.CC.009_3. ANEXO 7
COO-SPE-1007-03



s.p. química, s.a.

DOMICILIO:
Ctra. Foces-Vinyola, km 4,1
Tel. (34) 077 85 00 26
Teléfax (34) 077 85 05 21
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 78
43330 - RIUDOMS (Tara) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 12 JANUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (98 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.7 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.30 %	SPA-1007-04
Water (KF):	≤0.5%	0.16 %	SPA-1007-04
Formaldehyde:	≤200 ppm	138 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive Index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

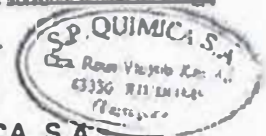
Stabilizers: 0.02 % SODIUM EDTA
0.02 % PROPYL GALLATE
0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopoeia
The product is manufactured from 100% vegetable glycerine origin.
The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/05 concerning the residual solvent control and inserted in the European Pharmacopoeia.

Manufacture Date: JANUARY 2016
Expiry Date: JANUARY 2019

SP QUÍMICA, S.A.
Quality Control



MP.CC.009_3. ANEXO 7
COD: SPE-1007-03



s.p. química, s.a.

DOMICILIO:
Ctra. Reus-Vinyols, km 4,7
Tel. (34) 977 85 00 26
Telefax (34) 977 85 05 21
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado P.D. EOX 78
43330 - RIUDOMS (Tarragona) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr: 160101025
Date: 25 JANUARY 2016

<u>CONCEPT</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>	<u>METHOD</u>
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.7 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.29 %	SPA-1007-04
Water (KF):	≤0.5%	0.17 %	SPA-1007-04
Formaldehyde:	≤200 ppm	129 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA

0.02 % PROPYL GALLATE

0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopeia.

The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents edited by EMEA and inserted in the European Pharmacopeia.

Manufacture Date: **JANUARY 2016**

Expiry Date: **JANUARY 2019**

SP QUÍMICA, S.A.

Quality Control





s.p. química, s.a.

DOMICILIO:
Ctra. Reus-Vinyols, km 4,1
Tel. (34) 977 85 00 26
Telefax (34) 977 85 05 21
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 78
43330 - RIUDOMS (Tgna) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr: 
Date: 27 JANUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.7 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.29 %	SPA-1007-04
Water (KF):	≤0.5%	0.20 %	SPA-1007-04
Formaldehyde:	≤200 ppm	123 ppm	SPA-1007-04
Peroxides:	≤15 ppm	1 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA

0.02 % PROPYL GALLATE

0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopeia.

The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents edited by EMEA and inserted in the European Pharmacopeia.

Manufacture Date: JANUARY 2016

Expiry Date: JANUARY 2019

SP QUÍMICA, S.A.

Quality Control





s.p. química, s.a.

DOMICILIO:
Ctra. Reus-Vinyols, km 4,1
Tel. (34) 977 85 00 26
Telefax (34) 977 85 05 21
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 78
43330 - RIUDOMS (Tgnal) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 29 JANUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.5 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.21 %	SPA-1007-04
Water (KF):	≤0.5%	0.16 %	SPA-1007-04
Formaldehyde:	≤200 ppm	109 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.4	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA

0.02 % PROPYL GALLATE

0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopeia.

The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents edited by EMEA and inserted in the European Pharmacopeia.

Manufacture Date: JANUARY 2016

Expiry Date: JANUARY 2019





s.p. química, s.a.

DOMICILIO:
Ctra. Pous Vinyals, km 4,1
Tel: (34) 977 85 00 86
Telèfax: (34) 077 85 05 21
43230 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 75
43230 - RIUDOMS (Tgna) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 4 FEBRUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.6 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.24 %	SPA-1007-04
Water (KF):	≤0.5%	0.18 %	SPA-1007-04
Formaldehyde:	≤200 ppm	118 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02% SODIUM EDTA

0.02% PROPYL GALLATE

0.01% THIODIPROPIONIC ACID

Specifications according to European Pharmacopeia.

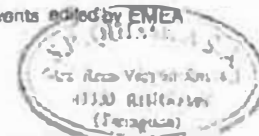
The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents **added by EMEA** and inserted in the European Pharmacopeia.

Manufacture Date: FEBRUARY 2016
Expiry Date: FEBRUARY 2019

SP QUÍMICA, S.A.
Quality Control



MP-CC 009_3 - ANEXO 7
COD: SPE-1007-03



s.p. química, s.a.

DOMINIO:
Ctra. Félix-Vieja, km 4.1
Tel. (01) 377 85 00 26
Fábrica (04) 977 85 05 21
13330 RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado P.O. Box 78
13330 RIUDOMS (Tarragona) SPAIN
Email: sppquimica@sppquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr:
Date: 9 FEBRUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (98 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.7 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.32 %	SPA-1007-04
Water (KF):	≤0.5%	0.15 %	SPA-1007-04
Formaldehyde:	≤200 ppm	189 ppm	SPA-1007-04
Peroxides:	≤15 ppm	2 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA

0.02 % PROPYL GALLATE

0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopoeia.

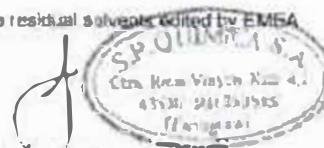
The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

This product is in compliance with the consensus guideline CPMP/ICH/283/95 concerning the residual solvents listed by EMA and inserted in the European Pharmacopoeia.

Manufacture Date: FEBRUARY 2016
Expiry Date: FEBRUARY 2019

SP QUÍMICA, S.A.
Quality Control



MP CC.009_3, ANEXO 7
COD: SPE-1007-03



s.p. química, s.a.

DOMICILIO:
C/Alf. Ros-Vinyola, km 4,1
Tel: (34) 877 85 00 26
Teléfax: (34) 877 85 05 31
43330 - RIUDOMS (Tarragona)

CORRESPONDENCIA:
Apartado / P.O. Box 78
43330 - RIUDOMS (Tarragona) SPAIN
E-mail: spquimica@spquimica.com

CERTIFICATE OF ANALYSIS

Product: STABILIZED GLYCEROL FORMAL
Batch nr: 1502020001
Date: 25 FEBRUARY 2016

CONCEPT	SPECIFICATIONS	RESULTS	METHOD
Appearance:	Clear, colourless liquid	Complies	SPA-1007-04
Solubility:	Miscible with water and ethanol (96 %)	Complies	SPA-1007-04
Assay (GC):	≥99.0%	99.6 %	SPA-1007-04
Identification A:	test	Complies	SPA-1007-04
Identification B:	test	Complies	SPA-1007-04
Identification C:	IR absorption	Complies	SPA-1007-04
Glycerol:	≤0.5%	0.25 %	SPA-1007-04
Water (KF):	≤0.5%	0.16 %	SPA-1007-04
Formaldehyde:	≤200 ppm	160 ppm	SPA-1007-04
Peroxides:	≤15 ppm	1 ppm	SPA-1007-04
Heavy Metals:	≤10 ppm	<10 ppm	SPA-1007-04
pH (10% w/v in water):	4.0 - 6.5	5.6	SPA-1007-04
Relative density:	1.210-1.220	1.218	SPA-1007-04
Refractive index:	1.445-1.455	1.450	SPA-1007-04

OBSERVATIONS

Stabilizers: 0.02 % SODIUM EDTA

0.02 % PROPYL GALLATE

0.01 % THIODIPROPIONIC ACID

Specifications according to European Pharmacopoeia.

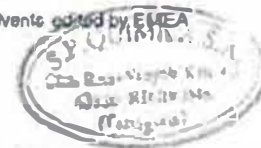
The product is manufactured from 100% vegetable glycerine origin.

The glycerine contains no detectable traces of GMOs.

The product is in compliance with the consensus guideline CPMP/ICH(283/05 concerning the residual solvents, adopted by EMEA and inserted in the European Pharmacopoeia.

Manufacture Date: FEBRUARY 2016
Expiry Date: FEBRUARY 2019

SP QUÍMICA, S.A.
Quality Control



MP-CC 009_3. ANEXO 7
COD: SPE-1007-03