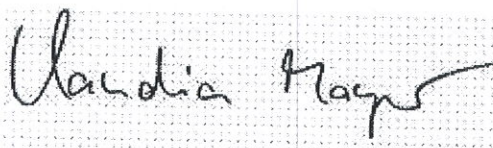


Certificate of Analysis

Product Name: TETRAHYDROFURAN
inhibitor-free, for HPLC, $\geq 99.9\%$
Product Number: 34865
Batch Number: STBH9164
Brand: Sigma-Aldrich
CAS Number: 109-99-9
Formula: C_4H_8O
Formula Weight: 72.11
Expiration Date: APR 2021
Quality Release Date: 04 JAN 2019

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS	COLORLESS
APPEARANCE (FORM)	LIQUID	LIQUID
COLOR (IN APHA)	≤ 10 APHA	5 APHA
TITRATABLE ACID	FREE ACID $\leq 0.002\%$ AS ACETIC ACID	0.001 %
PURITY (GC AREA %)	$\geq 99.90\%$	99.99 %
WATER (COULOMETR.)	$\leq 0.05\%$	$< 0.01\%$
RESIDUE (EVAPORATION)	$\leq 0.0005\%$	$< 0.0003\%$
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
UV-ABSORBANCE	≤ 0.005 AT 400NM	< 0.001
UV-ABSORBANCE	≤ 0.005 AT 350NM	< 0.001
UV-ABSORBANCE	≤ 0.0044 AT 315NM	< 0.001
UV-ABSORBANCE	≤ 0.02 AT 300NM	< 0.01
UV-ABSORBANCE	≤ 0.046 AT 275 NM	0.021
UV-ABSORBANCE	≤ 0.18 AT 250NM	0.14
UV-ABSORBANCE	≤ 0.26 AT 245NM	0.17
UV-ABSORBANCE	≤ 1.0 AT 212NM	0.5
PEROXIDES	$\leq 0.05\%$ (AS H_2O_2)	$< 0.01\%$



Claudia Mayer
Manager Quality Control
Steinheim, Germany



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Certificate of Analysis

Product Name: SILVER NITRATE
meets analytical specification of Ph. Eur., BP, USP, 99.8-100.5 %

Product Number: 10220

Batch Number: BCCB0818

Brand: Sigma-Aldrich

CAS Number: 7761-88-8

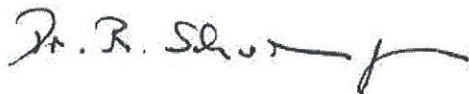
Formula: AgNO₃

Formula Weight: 169.87

Quality Release Date: 11 FEB 2019

Recommended Retest Date: JAN 2022

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	WHITE TO OFF WHITE	WHITE
APPEARANCE (FORM)	POWDER OR CRYSTALS	CRYSTALS
TITRATION (T) HCL 1M	99.8 - 100.5 %	99.8 %
SOLUBILITY (COLOR)	COMPLYING	COMPLYING
SOLUBILITY (TURBIDITY)	COMPLYING	COMPLYING
SOLUBILITY (METHOD)	ACC. TO PH.EUR.	ACC. TO PH.EUR.
PHARMACOPOEA TESTS	CORRESPONDS TO REQUIREMENTS	CORRESPONDS
Remarks on Pharmacopoea Test	ACIDIC OR ALKALIC REACTING IMPURITIES COMPLYING	ACIDIC OR ALKALIC REACTING IMPURITIES COMPLYING
	AL, PB, BI AND CU COMPLYING	AL, PB, BI AND CU COMPLYING
	IDENTITY COMPLYING	IDENTITY COMPLYING
TRACE ANALYSIS (ADDITIONAL TESTS)	SUBST. NOT PRECIPITATED BY HCL (AS SO ₄) ≤ 0.03%	≤ 0.01%
COPPER (ICP)	≤ 5 MG/KG	< 5 MG/KG
IRON (ICP)	≤ 5 MG/KG	< 5 MG/KG
LEAD (ICP)	≤ 20 MG/KG	< 20 MG/KG
TOTAL SULFUR AS SO ₄ (ICP)	≤ 100 MG/KG	≤ 20 MG/KG
NITRITE (NO ₂)	≤ 1000 MG/KG	≤ 500 MG/KG
RESIDUAL SOLVENTS (GLC-HS)	COMPLYING	COMPLIES



Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland



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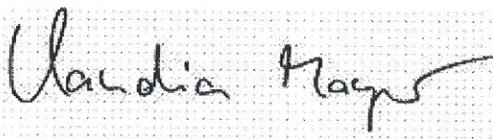
Product Name: SODIUM CHLORIDE
 puriss. p.a., ACS reagent, reag. ISO, reag. Ph. Eur., ≥ 99.5 %
Product Number: 31434
Batch Number: STBJ1927
Brand: Sigma-Aldrich
CAS Number: 7647-14-5
Formula: NaCl
Formula Weight: 58.44
Quality Release Date: 16 MAY 2019
Recommended Retest Date: DEC 2023

TEST	SPECIFICATION	RESULT
ARGENTOMETR. TITRATION	99.8 - 100.2 %	100.2 %
TITRATABLE ACID	$\leq 0.005\%$ FREE ACID (AS HCL)	$\leq 0.005\%$ FREE ACID (AS HCL)
TITRATABLE BASE	$\leq 0.005\%$ FREE ALKALI (AS NAOH)	$\leq 0.005\%$ FREE ALKALI (AS NAOH)
INSOLUBLE MATTER	≤ 0.005 %	≤ 0.005 %
SOLUBILITY (COLOR)	COLORLESS	COLORLESS
SOLUBILITY (TURBIDITY)	CLEAR	CLEAR
SOLUBILITY (METHOD)	5 % WATER, 25C	5 % WATER, 25C
PH	5.0 - 8.0	5.5
LOSS ON DRYING	$\leq 0.2\%$ LOSS ON DRYING, 130C	< 0.1 %
ACIDITY OR ALKALINITY	COMPLYING	COMPLYING
MISCELLANEOUS TESTS	$\leq 0.01\%$ MG, EARTHALKALIMETALS (AS CA \times 0.01 % CHLORATE, NITRATE (AS NO $_3$ -) ≤ 30 MG/KG	≤ 0.01 % ≤ 30 MG/KG
ACS SPECIFICATIONS	MEETS CURRENT ACS REQUIREMENTS	CONFORMS
ALUMINIUM	≤ 0.00002 %	< 0.00002 %
ARSEN	≤ 0.00005 %	< 0.00005 %
BARIUM	≤ 0.001 %	< 0.001 %
CALCIUM	≤ 0.002 %	< 0.002 %
IRON	≤ 0.0001 %	< 0.0001 %
POTASSIUM	≤ 0.005 %	< 0.005 %
MAGNESIUM	≤ 0.0005 %	< 0.0005 %
Heavy metals (by ICP-OES)	≤ 3 MG/KG	≤ 3 MG/KG
BROMIDE (BR)	≤ 50 MG/KG	≤ 50 MG/KG



Certificate of Analysis

IODIDE (I)	≤ 10 MG/KG	≤ 10 MG/KG
NITRITE (NO ₂)	COMPLYING	COMPLYING
TOTAL NITROGEN	≤ 10 MG/KG	≤ 10 MG/KG
PHOSPHATE (PO ₄)	≤ 5 MG/KG	≤ 5 MG/KG
SULFATE (SO ₄)	≤ 10 MG/KG	≤ 10 MG/KG
HEXACYANOFERRATES-TRACES	≤ 1 MG/KG	≤ 1 MG/KG



Claudia Mayer
Manager Quality Control
Steinheim, Germany



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Certificate of Analysis

Product Name: ACETIC ACID
puriss. p.a., ACS reagent, reag. ISO, reag. Ph. Eur., >= 99.8 %
Product Number: 33209
Batch Number: STBJ0375
Brand: Sigma-Aldrich
CAS Number: 64-19-7
Formula: CH₃CO₂H
Formula Weight: 60.05
Quality Release Date: 30 JAN 2019
Recommended Retest Date: JUL 2022

TEST	SPECIFICATION	RESULT
COLOR (IN APHA)	≤ 10 APHA	< 10 APHA
TITRATABLE BASE	≤ 0.0004 MEQ/G	< 0.0004 MEQ/G
ASSAY	≥ 99.8 %	99.9 %
PURITY (GC AREA %)	≥ 99.8 %	> 99.9 %
GC MINOR COMPONENT 1 (AREA %)	≤ 0.01 % ACETIC ANHYDRIDE	< 0.01 %
FREEZING POINT	≥ 16.3 DEG C	16.4 DEG C
BOILING POINT	117 - 119 C	117 C
DILUTION TEST	MIXABLE WITH H ₂ O: COMPLYING	COMPLYING
WATER	≤ 0.4 %	0.1 %
RESIDUE (EVAPORATION)	≤ 0.0005 %	< 0.0005 %
APPEARANCE	COMPLYING	COMPLYING
REDUCING SUBSTANCES	KMNO ₄ RED. SUBSTANCES: COMPLYING	COMPLYING
RESIDUAL SOLVENTS	PASS	COMPLYING
ACETALDEHYDE	≤ 0.0002 %	< 0.0002 %
HEAVY METALS	≤ 0.00005 % (AS PB)	< 0.00005 %
PROOF OF IDENTITY	IDENTITY CORRESPONDS	COMPLYING
MISCELLANEOUS TESTS	IDENTITY USP: COMPLYING	COMPLYING
SILVER	≤ 0.000001 %	< 0.000001 %
ALUMINIUM	≤ 0.000005 %	< 0.000005 %
ARSEN	≤ 0.000001 %	< 0.000001 %



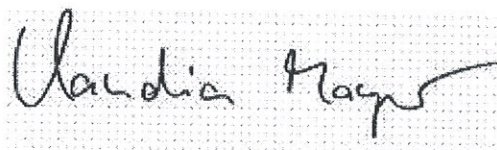
Certificate of Analysis

BARIUM	≤ 0.000001 %	< 0.000001 %
BERYLLIUM	≤ 0.000001 %	< 0.000001 %
BISMUTH	≤ 0.00001 %	< 0.00001 %
CALCIUM	≤ 0.00002 %	< 0.00002 %
CADMIUM	≤ 0.000002 %	< 0.000002 %
COBALT	≤ 0.000001 %	< 0.000001 %
CHROMIUM	≤ 0.000005 %	< 0.000005 %
COPPER	≤ 0.000001 %	< 0.000001 %
IRON	≤ 0.00002 %	< 0.00002 %
GERMANIUM	≤ 0.000005 %	< 0.000005 %
POTASSIUM	≤ 0.00001 %	< 0.00001 %
LITHIUM	≤ 0.000001 %	< 0.000001 %
MAGNESIUM	≤ 0.00001 %	< 0.00001 %
MANGANESE	≤ 0.000001 %	< 0.000001 %
MOLYBDENUM	≤ 0.000002 %	< 0.000002 %
SODIUM	≤ 0.00005 %	< 0.00005 %
NICKEL	≤ 0.000005 %	< 0.000005 %
LEAD	≤ 0.000002 %	< 0.000002 %
STRONTIUM	≤ 0.000001 %	< 0.000001 %
TITANIUM	≤ 0.000001 %	< 0.000001 %
THALLIUM	≤ 0.000005 %	< 0.000005 %
VANADIUM	≤ 0.000001 %	< 0.000001 %
ZINC	≤ 0.000005 %	< 0.000005 %



Certificate of Analysis

ZIRCONIUM	≤ 0.00001 %	< 0.00001 %
CHLORIDE (CL)	≤ 0.00005 %	< 0.00005 %
PHOSPHATE (PO4)	≤ 0.00005 %	< 0.00005 %
SULFATE (SO4)	≤ 0.00005 %	< 0.00005 %



Claudia Mayer
Manager Quality Control
Steinheim, Germany



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3050 Spruce Street, Saint Louis, MO 63103, USA

Website: www.sigmaaldrich.comEmail USA: techserv@sial.comOutside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:

Potassium bromide – anhydrous, free-flowing, Redi-Dri™, ACS reagent, ≥99%

Product Number: 746444
Batch Number: MKCH9997
Brand: SIGALD
CAS Number: 7758-02-3
Formula: BrK
Formula Weight: 119.00 g/mol
Quality Release Date: 16 APR 2019

KBr

Test	Specification	Result
Appearance (Color)	White	White
Appearance (Form)	Powder	Powder
X-Ray Diffraction	Conforms to Structure	Conforms
Titration by AgNO ₃ %KBr	≥ 99.0 %	99.4 %
Insoluble Matter C= 13.3%, H ₂ O	≤ 0.005 %	0.005 %
Barium	≤ 0.002 %	< 0.001 %
Bromate	≤ 0.001 %	< 0.001 %
Chloride Content	≤ 0.2 %	< 0.2 %
Iron (Fe)	≤ 5 ppm	< 1 ppm
Heavy Metals by ICP-OES	≤ 5 ppm	< 2 ppm
Iodide	≤ 0.001 %	< 0.001 %
Iodate	≤ 0.001 %	< 0.001 %
Sodium (Na)	≤ 0.02 %	< 0.02 %
Calcium (Ca)	≤ 0.002 %	< 0.001 %
Magnesium (Mg)	≤ 0.001 %	< 0.001 %
pH C= 5%, H ₂ O at 25 Degrees Celsius	5.0 - 8.8	8.2
Sulfate (SO ₄)	≤ 0.005 %	< 0.005 %
Meets ACS Requirements	Current ACS Specification	Conforms

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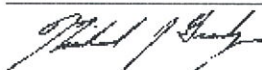


3050 Spruce Street, Saint Louis, MO 63103, USA

Website: www.sigmaaldrich.comEmail USA: techserv@sial.comOutside USA: eurtechserv@sial.com

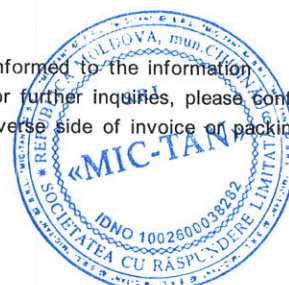
Certificate of Analysis

Product Number: 746444
Batch Number: MKCH9997



Michael Grady, Manager
Quality Control
Milwaukee, WI US

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Certificate of Analysis

Product Name: (+)-MENTHOFURAN
analytical standard
Product Number: 63661
Batch Number: BCBT7533
Brand: Sigma-Aldrich
CAS Number: 17957-94-7
Formula: $C_{10}H_{14}O$
Formula Weight: 150.22
Storage Temperature: 2-8 C
Expiration Date: JUN 2020
Quality Release Date: 05 OCT 2017

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS TO VERY FAINT YELLOW AND COLORLESS TO VERY FAINT GREEN-YELLOW	FAINT GREEN-YELLOW
APPEARANCE (FORM)	LIQUID	LIQUID
PURITY (GC AREA %)	≥ 99.0 %	99.6 %
SPECIFIC ROTATION (20/D)	100.0 ± 2.0 DEGREES	99.4 DEGREES
CONCENTRATION	NEAT	NEAT
REFRACTIVE INDEX N20/D	1.483 - 1.485	1.485
PROTON NMR SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS



Dr. Claudia Geitner
Manager Quality Control
Buchs, Switzerland

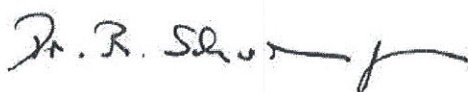


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Certificate of Analysis

Product Name: (-)-ISOPULEGOL
analytical standard
Product Number: 59770
Batch Number: BCCB1587
Brand: Sigma-Aldrich
CAS Number: 89-79-2
Formula: C₁₀H₁₈O
Formula Weight: 154.25
Expiration Date: JAN 2022
Quality Release Date: 21 FEB 2019

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS	COLORLESS
APPEARANCE (FORM)	LIQUID	LIQUID
PURITY (GC AREA %)	≥ 99.0 %	99.9 %
ENANTIOMERIC RATIO	≥ 99.5 : 0.5 (GC)	100.0 % (GC)
SPECIFIC ROTATION (20/D)	-22.0 ± 0.5 DEGREES	-22.1 DEGREES
CONCENTRATION	NEAT	NEAT
REFRACTIVE INDEX N20/D	1.471 - 1.473	1.472
PROTON NMR SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS



Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland

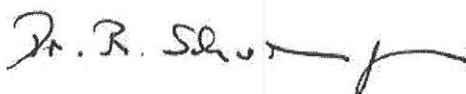


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Certificate of Analysis

Product Name: SULFANILIC ACID
ACS reagent, 99 %
Product Number: 251917
Batch Number: BCCB2397
Brand: Sigma-Aldrich
CAS Number: 121-57-3
Formula: 4-(H₂N)C₆H₄SO₃H
Formula Weight: 173.19
Quality Release Date: 02 MAY 2019

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	WHITE TO BEIGE TO GRAY	OFF WHITE
APPEARANCE (FORM)	POWDER	POWDER
TITRATION (T) NAOH 0.1M	98.5 - 101.5 %	99.8 %
SOLUBILITY (COLOR)	COLORLESS TO ALMOST COLORLESS	ALMOST COLORLESS
SOLUBILITY (TURBIDITY)	0.02 % INSOLUBLE MATTER (MAXIMUM)	CLEAR
SOLUBILITY (METHOD)	C=5G IN50 ML 5% SODIUMCARBONATE	C=5G IN50 ML 5% SODIUMCARBONATE
SULFATED ASH	≤ 0.01 %	0.008 %
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
CHLORIDE (CL)	0.002 % (MAXIMUM)	< 0.002 %
NITRITE (NO ₂)	0.5 PPM (MAXIMUM)	< 0.5 PPM
SULFATE (SO ₄)	0.01 % (MAXIMUM)	< 0.01 %



Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland



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Certificate of Analysis

Product Name: D-MANNITOL
tested according to Ph Eur
Product Number: 17311
Batch Number: BCCB0509
Brand: Sigma-Aldrich
CAS Number: 69-65-8
Formula: $C_6H_{14}O_6$
Formula Weight: 182.17
Quality Release Date: 14 MAY 2019
Recommended Retest Date: MAY 2023

TEST	SPECIFICATION	RESULT
PHARMACOPOEA TESTS	CORRESPONDS TO REQUIREMENTS	TESTED ACCORDING TO PH.EUR.9.8
IDENTIFICATION C	IR	CORRESPONDS
APPEARANCE OF SOLUTION	CLEAR, COLORLESS	CLEAR, COLORLESS
MELTING POINT	165 - 170 C	168 C
REDUCING SUGARS	MAX. 0.1 % (CALC. AS GLUCOSE EQUIVALENT)	<=0.1 %
RELATED SUBSTANCES	LC: SORBITOL MAX. 2.0 %; SUM OF MALTITOL AND ISOMALT MAX. 2.0 %; UNSPECIFIED IMPURITIES EACH MAX. 0.10 %; TOTAL MAX. 2.0 %	SORBITOL 0.9 %, SUM OF MALTITOL AND ISOMALT 0.07 %; UNSPECIFIED IMPURITIES 0.09 %; TOTAL 1.0 %
RESIDUAL SOLVENTS	CORRESPONDS	CORRESPONDS
CONDUCTIVITY	MAX. 20 US/CM	1.9 US/CM
HEAVY METALS	CORRESPONDS	ELEMENTAL IMPURITIES ACCORDING TO ICH Q3D ARE NOT LIKELY TO BE PRESENT
LOSS ON DRYING	MAX. 0.5 %	0.08 %
MICROBIAL CONTAMINATION	TAMC <=1000 CFU/G; TYMC <=100 CFU/G; ABSENCE OF E.COLI; ABSENCE OF SALMONELLA	TAMC <10 CFU/G; TYMC <10 CFU/G; ABSENCE OF E.COLI; ABSENCE OF SALMONELLA
ASSAY	97.0 - 102.0 % (DRIED SUBSTANCE)	98.9 %
REMARKS	NOT SUITABLE FOR USE IN THE MANUFACTURE OF PARENTERAL PREPARATIONS	

Dr. R. Schwenninger

Dr. Reinhold Schwenninger

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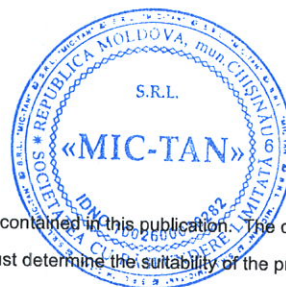


Product Name:	HEXANE for HPLC, >= 97.0 % GC
Product Number:	34859
Batch Number:	STBH9895
Brand:	Sigma-Aldrich
CAS Number:	110-54-3
Formula:	CH ₃ (CH ₂) ₄ CH ₃
Formula Weight:	86.18
Expiration Date:	DEC 2023
Quality Release Date:	05 APR 2019

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS	COLORLESS
APPEARANCE (FORM)	LIQUID	LIQUID
TITRATABLE ACID	FREE ACID ≤ 0.001 % AS CH ₃ COOH	0.001 %
PURITY (GC AREA %)	≥ 97.00 %	98.11 %
REFRACTIVE INDEX N ₂₀ /D	1.373 - 1.377	1.374
WATER (COULOMETR.)	≤ 0.010 %	0.002 %
RESIDUE (EVAPORATION)	≤ 0.0005 %	< 0.0002 %
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
UV-ABSORBANCE	≤ 0.01 AT 250NM	0.01
UV-ABSORBANCE	≤ 0.1 AT 225NM	< 0.1
UV-ABSORBANCE	≤ 0.7 AT 220NM	0.1

Claudia Wagner

Claudia Mayer
Manager Quality Control
Steinheim, Germany



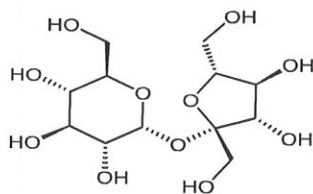
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Certificate of Analysis

ISO GUIDE 34
ANAB Cert# AR-1470

ISO/IEC 17025
ANAB Cert# AT-1467

SUCROSE CERTIFIED REFERENCE MATERIAL



CERTIFIED PURITY: 99.98%, $U_{\text{crm}} = \pm 0.2\% \text{ } k = 2$
(Mass Balance/as is basis)

NOMINAL PACKAGE SIZE: 1g

CATALOG #: PHR1001

LOT #: LRAA6758

CERTIFICATE VERSION: LRAA6758.4

ISSUE DATE: 10 April 2018

*Note: Certificates may be updated due to Pharmacopeial Lot changes or the availability of new data.
Check our website at: www.sigma-aldrich.com for the most current version.*

CRM EXPIRATION: 31 December 2019 (Proper Storage and Handling Required).

RECEIPT DATE: _____

Note: this space is provided for convenience only and its use is not required.

STORAGE: Store at Room Temperature/Protect from Light, keep container tightly closed. Attachment of a 20 mm aluminum crimp seal recommended for unused portions.

CHEMICAL FORMULA: $\text{C}_{12}\text{H}_{22}\text{O}_{11}$

MW: 342.3

PHYSICAL DESCRIPTION: White powder in amber vial

CAS #: 57-50-1

HAZARDS: Read Safety Data Sheet before using. All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel.

SIGMA-ALDRICH®



INSTRUCTIONS FOR USE: Do not dry, use on the as is basis. The internal pressure of the container may be slightly different from the atmospheric pressure at the user's location. Open slowly and carefully to avoid dispersion of the material. This material is intended for Laboratory Use only. Not for drug, household or other uses.

TRACEABILITY ASSAY

Comparative assay demonstrates direct traceability to Pharmacopeial Standards

METHOD: HPLC (ref.: Cranberry Liquid Preparation, Current Compendial Monographs)

ASSAY vs. USP REFERENCE STANDARD (as is basis)

<u>ASSAY VALUE</u>	<u>vs. USP LOT</u>
100.9%	R04311
	Labeled Content = 1.000 mg/mg

ASSAY vs. EP CRS (as is basis)

<u>ASSAY VALUE</u>	<u>vs. EP BATCH</u>
100.9%	2.0
	Labeled Content = None
	Assigned Content = 99.6%*

*The assigned content of the EP CRS was determined by assay against the USP Reference Standard

Column: Supelcogel Ca, 7.8 x 300mm

Column Temperature: 55 °C

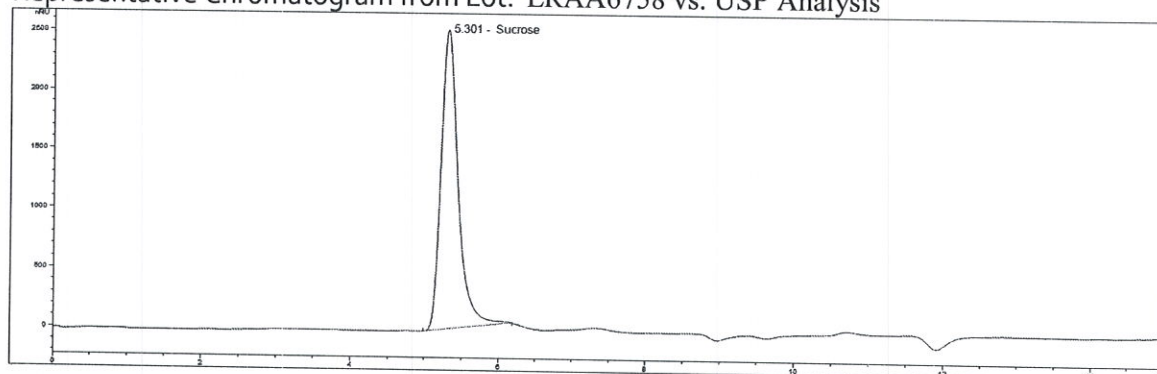
Mobile Phase: DI Water

Flow: 1.0 mL/min

Injection: 10 µL

Detector: Refractive Index at 55 °C

Representative Chromatogram from Lot: LRAA6758 vs. USP Analysis



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METHOD: HPLC (ref.: Cranberry Liquid Preparation, Current Compendial Monographs)

ASSAY vs. BP CRS (as is basis)

<u>ASSAY VALUE</u>	<u>vs. BP BATCH</u>
101.7%	2919
	Labeled Content = 99.7%

Column: Supelcogel Ca, 7.8 x 300 mm

Column Temperature: 55°C

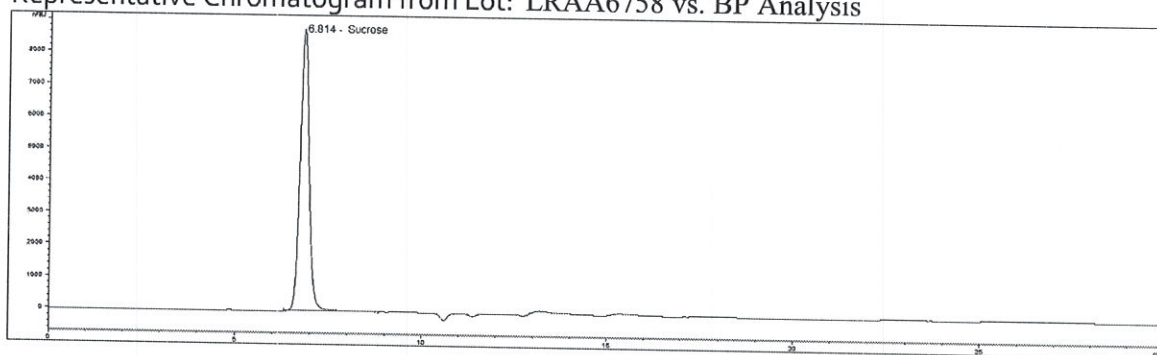
Mobile Phase: Water

Flow: 0.8mL/min

Injection: 25 µL

Detector: Refractive Index

Representative Chromatogram from Lot: LRAA6758 vs. BP Analysis



TOTAL ORGANIC CARBON ANALYSIS vs. USP REFERENCE STANDARD

Specification: None

METHOD: TOC (ref.: USP <643>)

Instrument: Shimadzu TOC-V WS

Solvent: Reagent Water

Concentration: 0.024 mg/mL

Response Efficiency: 99.2 %

<u>ASSAY VALUE</u>	<u>vs. USP LOT</u>
41.9% (As Carbon)	R04311
99.5% (As Sucrose)	Labeled Content = 1.000 mg/mg

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PURITY DETERMINATION BY MASS BALANCE

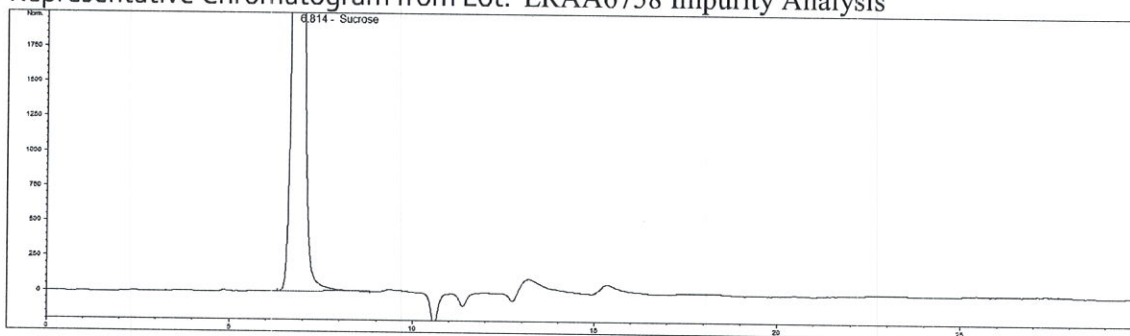
CHROMATOGRAPHIC IMPURITY ANALYSIS

METHOD: HPLC (ref.: Adapted from Cranberry Liquid Preparation, Current Compendial Monographs)

See Assay

Impurities Detected: **None**

Representative Chromatogram from Lot: LRAA6758 Impurity Analysis



RESIDUAL SOLVENTS

Method: GC-MS Headspace (ref.: Residual Solvents USP <467>)

Column: DB-1301

Carrier gas: He

Flow: 1.2 mL/min

Split Ratio: 1:5

Injection/Temperature: 1 μ L/250°C

Temperature Program: 40°C for 20min, 10°C/min to 240°C, hold 20min

Solvents Detected: None

LOSS ON DRYING/VOLATILES

Method: Oven at 105°C

Mean of three measurements, Loss = **0.02%**

RESIDUE ANALYSIS

Method: Sulfated Ash

Sample Size: ~100 mg

Mean of three measurements, Residue = **0.001%**

CERTIFIED PURITY BY MASS BALANCE [100% - Impurities (normalized)]

99.98% $U_{\text{crm}} = \pm 0.2\%$, $k = 2$
(as is basis)

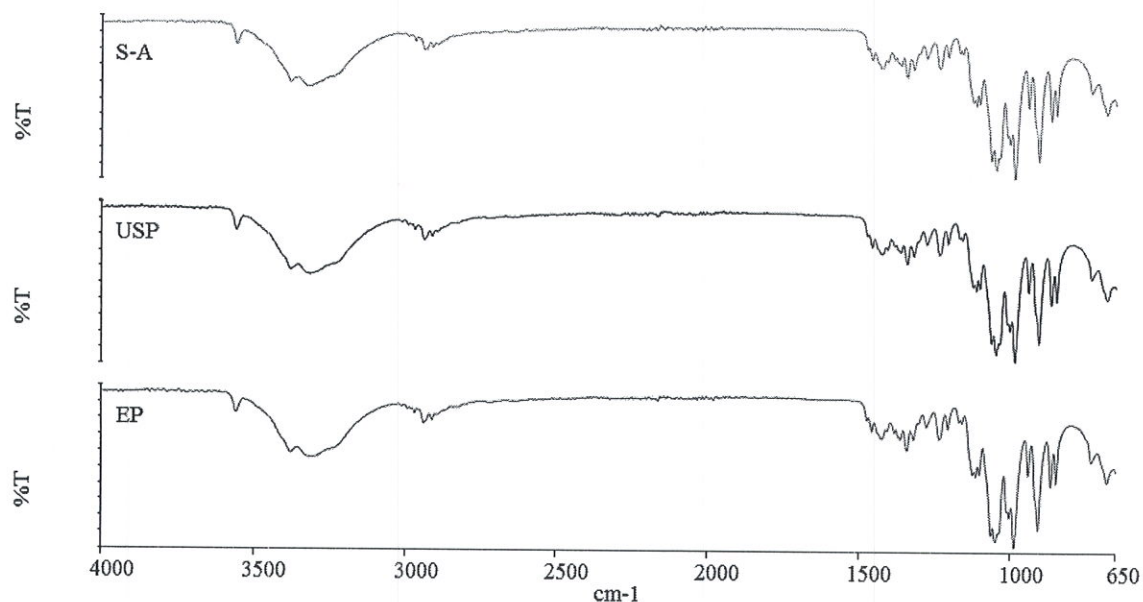
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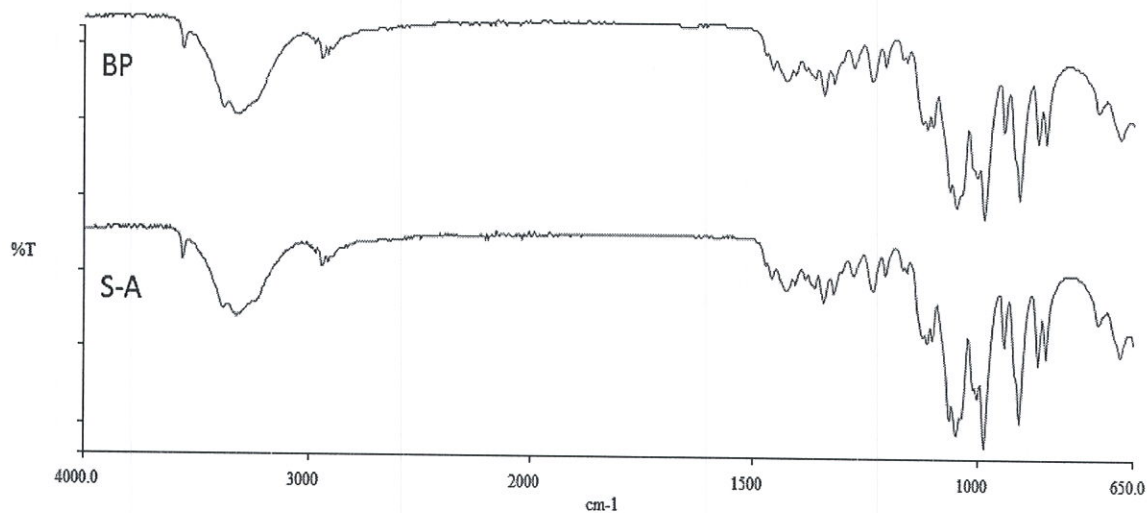
IDENTIFICATION TESTS

INFRARED SPECTROPHOTOMETRY (Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)



— Sucrose S-A Lot LRAA6758
— Sucrose USP Lot R04311
— Sucrose EP Batch 2.0

PERKIN ELMER SPECTRUM 100
SAMPLING: UNIVERSAL ATR



— Sucrose BP Batch 2919
— Sucrose S-A Lot LRAA6758

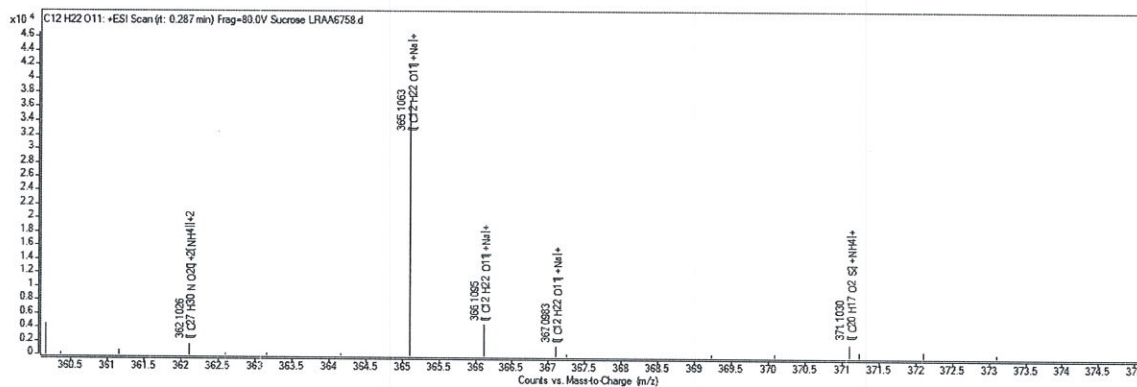
PERKIN ELMER SPECTRUM 100
SAMPLING: UNIVERSAL ATR

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MASS SPECTRUM

Method: HR-QTOF; 4.0 kV ESI+; temperature: 325 °C

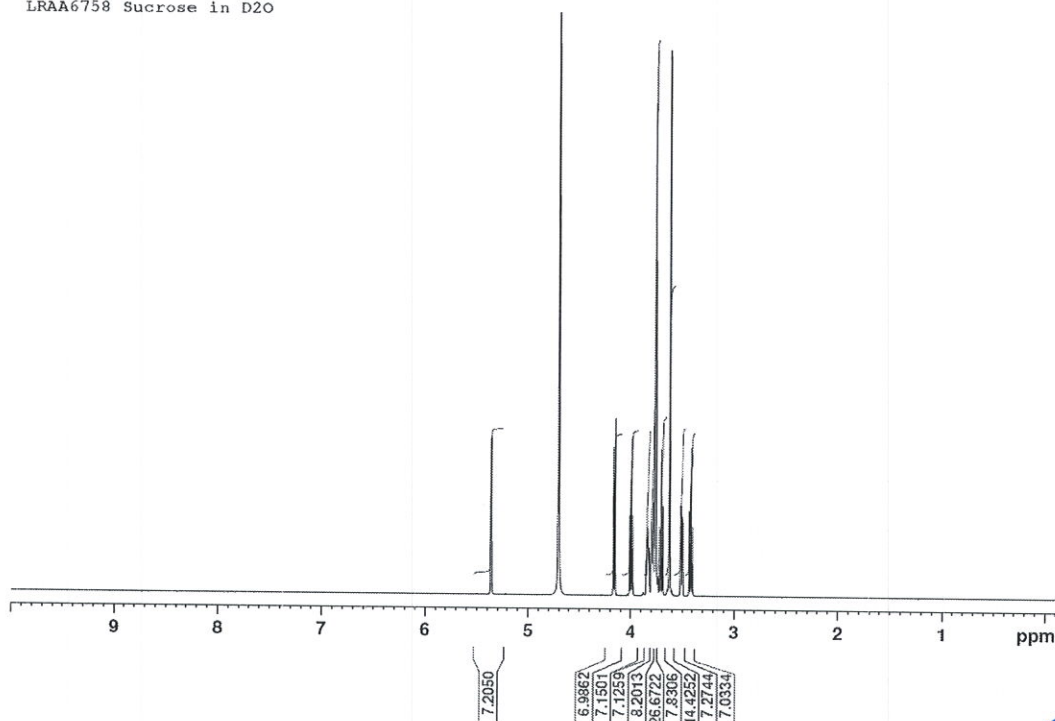


Theoretical value: 365.1060 m/z [M+Na]⁺

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

¹H NMR (Data provided by an external laboratory; not in scope of accreditation)

LRAA6758 Sucrose in D₂O



Consistent with structure

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ELEMENTAL ANALYSIS (Data provided by an external laboratory; not in scope of accreditation)

Exeter Analytical 440 Elemental Analyzer

Combustion method

%	Theoretical	Result 1	Result 2	Mean
C	42.11	42.31	42.30	42.31
H	6.48	6.33	6.28	6.31

OPTICAL ROTATION

Specification: +66.3° to +67.0° (USP)

Perkin Elmer Polarimeter 343

Wavelength: 589 nm

Concentration: 0.26 g/mL

Cell Path: 100 mm

Mean of seven Measurements = +66.7°

HOMOGENEITY ASSESSMENT

Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.

Analytical Method: HPLC

Sample size: ~50 mg

UNCERTAINTY STATEMENT

Uncertainty values in this document are expressed as Expanded Uncertainty (U_{crm}) corresponding to the 95% confidence interval. U_{crm} is derived from the combined standard uncertainty multiplied by the coverage factor k , which is obtained from a t -distribution and degrees of freedom. The components of combined standard uncertainty include the uncertainties due to characterization, homogeneity, long term stability, and short term stability (transport). The components due to stability are generally considered to be negligible unless otherwise indicated by stability studies.

STABILITY ASSESSMENT

Significance of the stability assessment will be demonstrated if the analytical result of the study and the range of values represented by the Expanded Uncertainty do not overlap the result of the original assay and the range of its values represented by the Expanded Uncertainty. The method employed will usually be the same method used to characterize the assay value in the initial evaluation.



Long Term Stability Evaluation - An assessment, or re-test, versus a Compendial Reference Standard may be scheduled, within the 3 year anniversary date of a release of a Secondary Standard. The re-test interval will be determined on a case-by-case basis.
Short Term Stability Study - It is useful to assess stability under reasonably anticipated, short term transport conditions by simulating exposure of the product to humidity and temperature stress. This type of study is conducted under controlled conditions of elevated temperature and humidity.



QC Manager



QA Supervisor

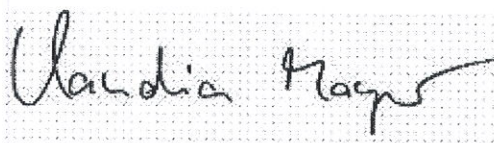
APPENDIX

Original Release Date:	22 January 2015
Stability Test Date:	31 July 2017
Requalification Test Date:	31 July 2017
Requalification Test Date:	10 April 2018

Certificate of Analysis

Product Name: ACETALDEHYDE DIETHYL ACETAL
99 %
Product Number: A902
Batch Number: STBH6412
Brand: Aldrich
CAS Number: 105-57-7
Formula: $\text{CH}_3\text{CH}(\text{OC}_2\text{H}_5)_2$
Formula Weight: 118.17
Quality Release Date: 07 JUN 2018

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS	COLORLESS
APPEARANCE (FORM)	LIQUID	LIQUID
PURITY (GC AREA %)	≥ 98.5 %	99.4 %
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS



Claudia Mayer
Manager Quality Control
Steinheim, Germany

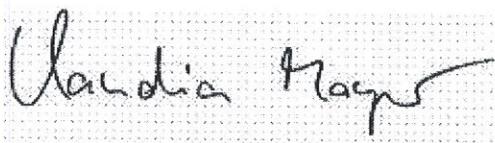


Sigma-Aldrich warrants that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.

Certificate of Analysis

Product Name: ETHANOLAMINE
Product Number: ACS reagent, >= 99.0 %
Batch Number: 398136
Batch Number: STBJ2248
Brand: Sigma-Aldrich
CAS Number: 141-43-5
Formula: $\text{NH}_2\text{CH}_2\text{CH}_2\text{OH}$
Formula Weight: 61.08
Quality Release Date: 10 MAY 2019
Recommended Retest Date: MAY 2021

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS	COLORLESS
APPEARANCE (FORM)	LIQUID OR VISCOUS LIQUID	LIQUID
COLOR (IN APHA)	≤ 15 APHA	< 10 APHA
PURITY (GC AREA %)	≥ 99.0 %	> 99.9 %
WATER	≤ 0.3 %	0.1 %.
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
HEAVY METALS	≤ 5 PPM (AS PB)	< 5PPM
ACS SPECIFICATIONS	MEETS CURRENT ACS REQUIREMENTS	CONFORMS
IRON (ICP)	≤ 5 MG/KG	< 2 MG/KG



Claudia Mayer
Manager Quality Control
Steinheim, Germany

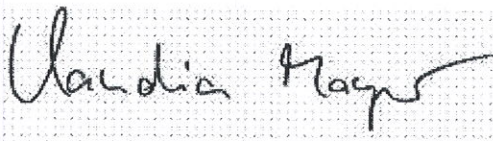


Sigma-Aldrich warrants that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.

Certificate of Analysis

Product Name: THYMOL
meets analytical specification of Ph. Eur., BP, NF, 99-101 %
Product Number: 16254
Batch Number: STBH4736
Brand: Sigma-Aldrich
CAS Number: 89-83-8
Formula: $2-[(CH_3)_2CH]C_6H_3-5-(CH_3)OH$
Formula Weight: 150.22
Expiration Date: AUG 2020
Quality Release Date: 22 FEB 2018

TEST	SPECIFICATION	RESULT
ASSAY	99 - 101 %	99.8 %
MELTING POINT	REPORT RESULTS	49.2-50.4 DEG C C
RESIDUE (EVAPORATION)	≤ 0.05 %	< 0.01 %
APPEARANCE OF SOLUTION	COMPLYING	COMPLYING
ACIDITY	COMPLYING	COMPLYING
RELATED SUBSTANCES	GC: COMPLYING	COMPLYING
RESIDUAL SOLVENTS	COMPLYING	COMPLYING



Claudia Mayer
Manager Quality Control
Steinheim, Germany



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