





Certificate of Analysis

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PRODUCT NAME Rutin Trihydrate

PART NUMBER 00018430

STANDARD TYPE Primary (P) – Compendial Traceable

LOT NUMBER 00018430-002694

REPORT NUMBER CDXA-RSS-7158-02

SAMPLE NUMBER CDXA-16-003954

DATE OF SAMPLE 03/29/2016 **DATE OF REEVALUATION** 09/21/2020

DATE OF REPORT 10/16/2020

CHEMICAL NAMES

3-[[6-O-(6-Deoxy-α-L-mannopyranosyl)-β-D-glucopyranosyl]oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4H-1-benzopyran-4-one hydrate (1:3)

CHEMICAL FORMULA C₂₇H₃₀O₁₆ • 3H₂O

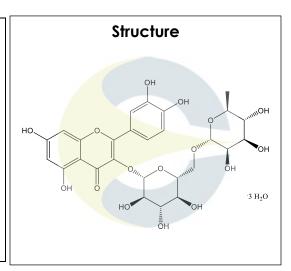
MOLECULAR WEIGHT (MW) 664.56

CHEMICAL FAMILY Flavonoids

CAS NUMBER [250249-75-3]

EC#(EINECS) 684-230-2

RTECS N/A



ANALYTICAL RESULTS

TEST	METHOD	SPECIFICATION	RESULT
Adjusted Purity	NA	≥ 85%	89.3%
HPLC	0.700.10.2.METH22	≥ 90%	97.2%
NMR	4.5.3-CD-4.0-000338	Conforms to structure	Conforms to structure
Mass Spectrum	99.1-CDXA-2.0-000126	Conforms	Conforms
Residual Solvent	99.1-CD-9.0-000115	NA	ND
Water	0.700.12.37	NA	8.1%*
Appearance NA		NA	Yellow needles

ADJUSTED PURITY: 89.3% IS BASED ON (100 - 8.1 WATER - 0.0 SOLVENTS) X 97.2% HPLC

*Water result includes the bonded water of the hydrate form.

TRACEABLE SOURCE	LOT NUMBER	ASSAY RESULT
USP	R054J0	89.1% (as-is weight % of Rutin)







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STORAGE CONDITIONS

STORAGE Room Temperature in a dry place.

EXPIRATION DATE 09/2025 under the above conditions.

ANALYTICAL CONDITIONS

INSTRUMENT AGILENT 1260 HPLC UV-VIS (DAD); AGILENT 6510 QTOF

COLUMN Phenomenex Luna C18(2) 150 x 2.00 mm, 5 µm particle size

MOBILE PHASE A - 0.1% Trifluoroacetic acid in Milli-Q water, B - Acetonitrile;

Isocratic 5% B for 5 minutes, then increasing to 95% B over 20 minutes. Hold at

95% B for 15 minutes, then decreasing to 5% B over 1 minutes.

COLUMN TEMP. 60 °C

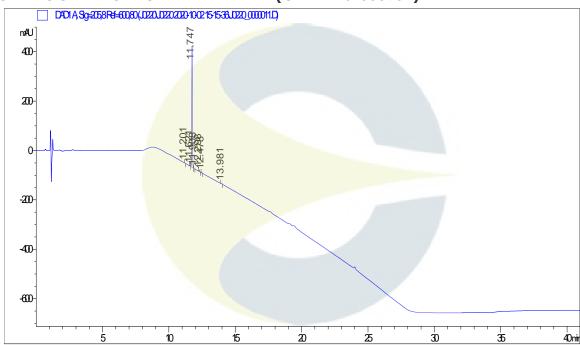
FLOW RATE 0.4 mL/minute

INJECTION VOL. 0.2 μL

INJECTION CONC. 1.1 mg/mL in Methanol

DETECTION $205 \pm 4 \text{ nm}$

HPLC CHROMATOGRAM OF RUTIN TRIHYDRATE (CDXA-16-003954)





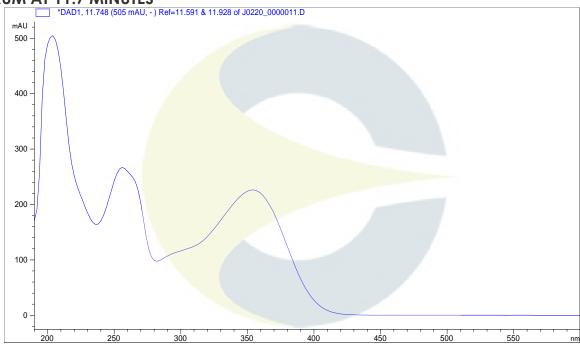




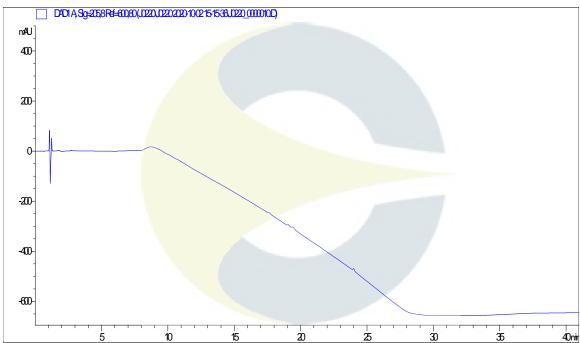
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UV SPECTRUM AT 11.7 MINUTES



HPLC CHROMATOGRAM OF BLANK





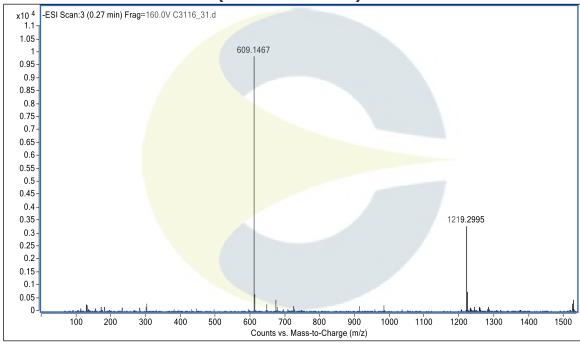




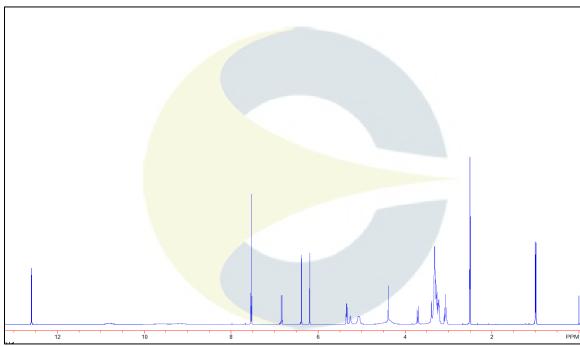
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MASS SPECTRUM OF RUTIN TRIHYDRATE (CDXA-16-003954)



1H-NMR SPECTRUM OF RUTIN TRIHYDRATE (CDXA-16-003954) IN DMSO-d6





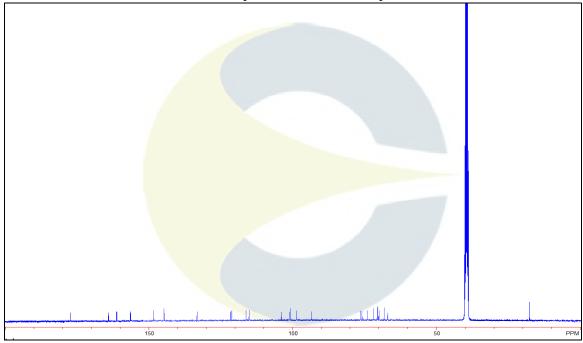




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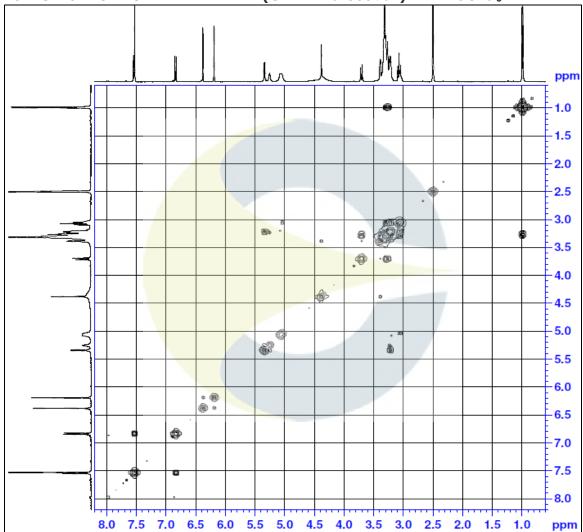




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REVISION HISTORY

Revision History	<u>Date of Revision</u>	Document/Changes
00	06/21/2016	New report
01	08/16/2017	Revision. Updated product and chemical names, chemical formula, molecular weight, structure, CAS number, EC#, and RTECS to reflect the trihydrate form. Removed melting point section.
02	10/16/2020	Material passed reevaluation by HPLC and KF. Updated EC#, analytical results, expiration date, analytical conditions, and chromatograms.