Food / Pharmaceutical
Newsletter
www.canberrachemicals.in

Diethylene Glycol CONTAMINATION !

The deaths of 66+ children in Gambia shook the world and more importantly the reason behind it, cough syrup made in India was to blame, as we go into this newsletter, DGCI updates WHO its findings.

This is not first time that the cough syrup deaths have been reported. Not just in India, deaths connected to DEG-Diethylene glycol contaminated syrup (would say unchecked or skipped test) have been reported in Panama, Bangladesh, Nigeria and United states as well.

In India it has happened in 1973, 1986, 1998, 2020 and latest 2022 Gambia and it is a moral responsibility of Pharma / Food industry to investigate the repeatability of issues indicating Route cause analysis failure. Food additives / Pharmaceutical ingredients have a limit set in products with known risks

Use of DEG is banned, but somehow this impurity find its way in formulations, even through other ingredients were it is assumed not to be generated during production, then in such case it is sure case of adulteration / contamination and negligence.

Propylene glycol considered to be cause of the incident has regulatory defined limits, however DEG it is not generated during process, indicating that the “Glycol” name can be one of cause of misbranding/mislabeling/economic advantages. Several Regulatory warnings have been issued on non – testing of DEG in Glycerine and related products.

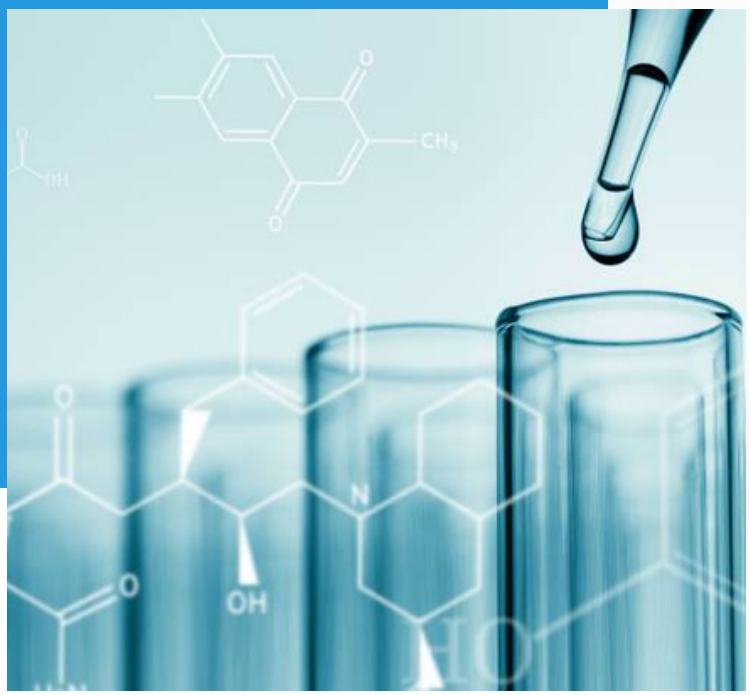
Canberra Chemicals has experience of this test as one of customer during its routine investigation from US market supplying goods to Korea market came across this contamination in year 2020, in products related to calcium carbonate at around 15 – 50 ppm against the prescribed limits of 2000 ppm in certain food additives, however since the product of concern was not eligible for the limits the source and elimination was to be done earliest as requested by customer.

In absence of test methods of accuracy, we immediately developed methods with our local public / FDA laboratory and found that contamination can have come in few samples’ fumes of brake fluids, or other environmental contaminations, we immediately tested all the grade and approved the new grade from the supplier based on testing and risk analysis.

The tests have now become a routine as this and likewise contaminants are present in environmental pilferages, though they have generally not detected in major cases and found not harmful to aquatic systems.

Calcium phosphates are using water and product DEG is water soluble, however we investigated by way of testing in all our products also

Risk analysis was done on Raw materials and the specifications as per Food / pharmaceutical regulations along with process flow was considered.



The Food industry approach of Chemical / Physical / Microbiological Risk analysis by way of probability and severity, gives a good control approach.

This assurance documents by Canberra Chemicals Team is only to build Trust on customers that

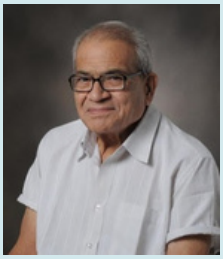
We have included lot of risk base approach in our production, resulting in safe products, this understanding and learning ability is credited to all our good customer who have kept us always on run to have continual improvement, and we assure that we are on track to achieve this.

The testing method validation and analysis was carried out by Mr. DB Dave and teammate Mr. Khodal

Prashant Patel

We stand with all the families in this difficult time.

Message from the Founder



I am glad for the intitiave taken by Canberra Chemicals Team to build a trust with customer supported by such Test validatations via sharing through news letter. Best wishes and hope such assuring newsletter covering environmental / product safety / Society upliftment topics will be covered in coming editions.
Happy new year wishes to readers.

Shri. B.C. Patel

Analysis of Diethylene Glycol / GCMS

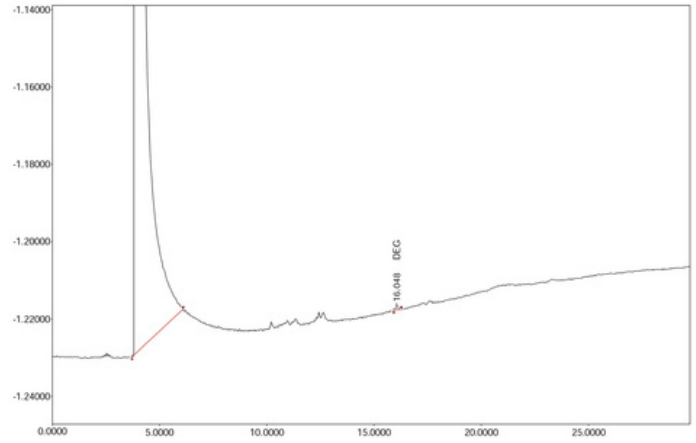
Analysis Report

< Analysis Information >

DATA FILE NAME : BAS388.RAW
Sample name : BAS 388
Method name :
Reporting Date : October 19, 2022 11:20 AM

BARODA ANALYTICAL SERVICES
SAMPLE NAME :- STD 50 PPM

< Chromatogram >



#	RT(min)	Peak name	Area(mV*sec)	Area%
1	3.818		47140.422	99.982
2	16.048	DEG	8.546	0.018

DEG Standard

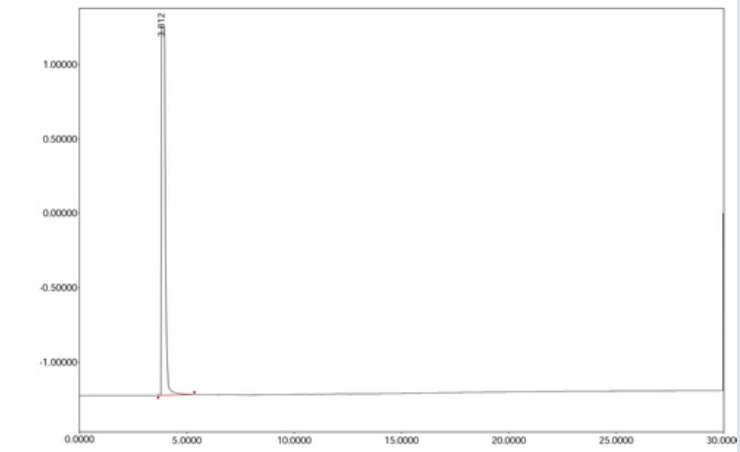
Analysis Report

< Analysis Information >

DATA FILE NAME : BAS389.RAW
Sample name : BAS 389
Method name :
Reporting Date : October 19, 2022 12:00 PM

BARODA ANALYTICAL SERVICES
SAMPLE NAME :- T-66/22

< Chromatogram >



#	RT(min)	Peak name	Area(mV*sec)	Area%
1	3.812		31974.578	100.000

TCP

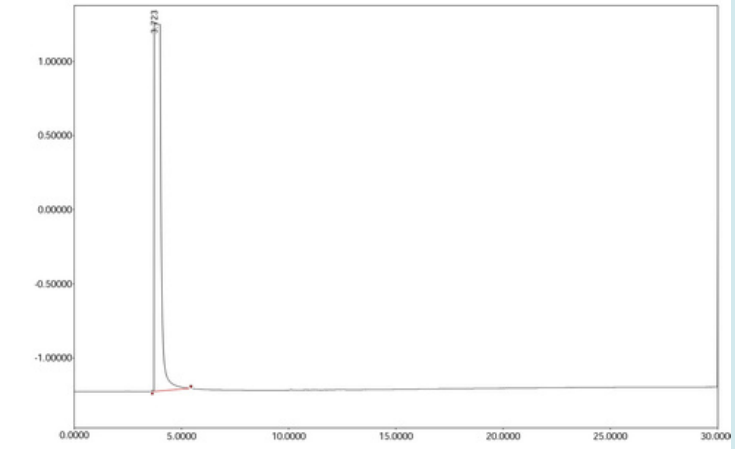
Analysis Report

< Analysis Information >

DATA FILE NAME : BAS390.RAW
Sample name : BAS 390
Method name :
Reporting Date : October 19, 2022 12:50 PM

BARODA ANALYTICAL SERVICES
SAMPLE NAME :- DA-98/22

< Chromatogram >



#	RT(min)	Peak name	Area(mV*sec)	Area%
1	3.723		53965.973	100.000

DCP - Anhydrous

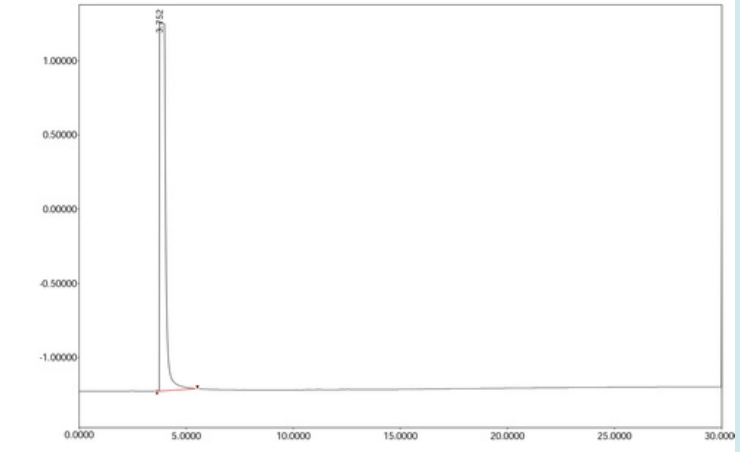
Analysis Report

< Analysis Information >

DATA FILE NAME : BAS391.RAW
Sample name : BAS 391
Method name :
Reporting Date : October 19, 2022 1:40 PM

BARODA ANALYTICAL SERVICES
SAMPLE NAME :- D-116/22

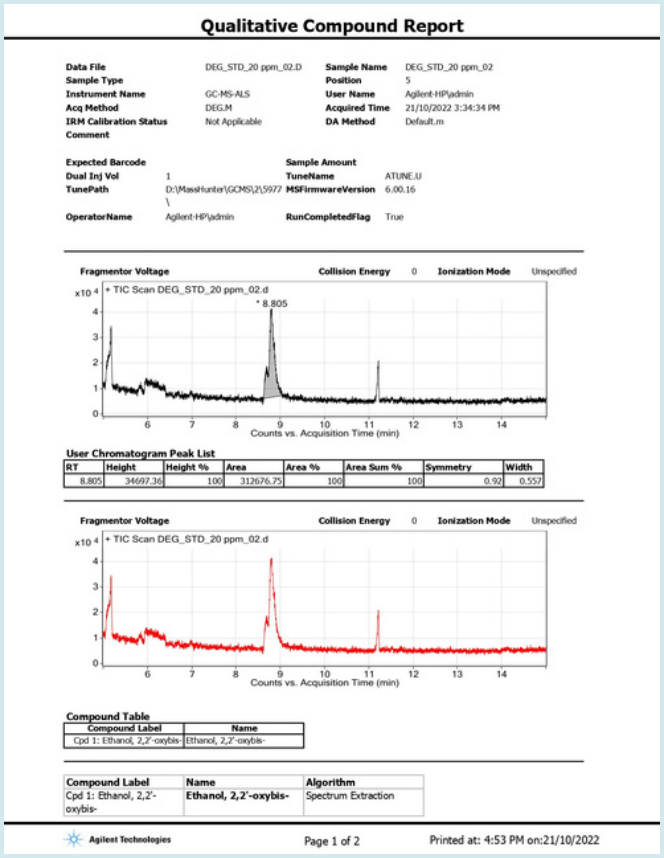
< Chromatogram >



#	RT(min)	Peak name	Area(mV*sec)	Area%
1	3.752		47885.598	100.000

DCP - Dihydrate

Analysis of Diethylene Glycol / GCMS



Qualitative Compound Report

Data File DEG_STD_20 ppm_02.D
Sample Name DEG_STD_20 ppm_02
Sample Type
Position 5
Instrument Name GC-MS-ALS
User Name Agilent-HP\admin
Acq Method DEG.M
Acquired Time 21/10/2022 3:34:34 PM
IRM Calibration Status Not Applicable
DA Method Default.m
Comment

Expected Barcode
Sample Amount
Dual Inj Vol 1
TuneName ATUNE.U
TunePath D:\MassHunter\GCMS\2\5977 \
MSFirmwareVersion 6.00.16
OperatorName Agilent-HP\admin
RunCompletedFlag True

Fragmentor Voltage Collision Energy 0 Ionization Mode Unspecified

User Chromatogram Peak List

RT	Height	Height %	Area	Area %	Area Sum %	Symmetry	Width
8.805	34697.36	100	312676.75	100	100	0.92	0.557

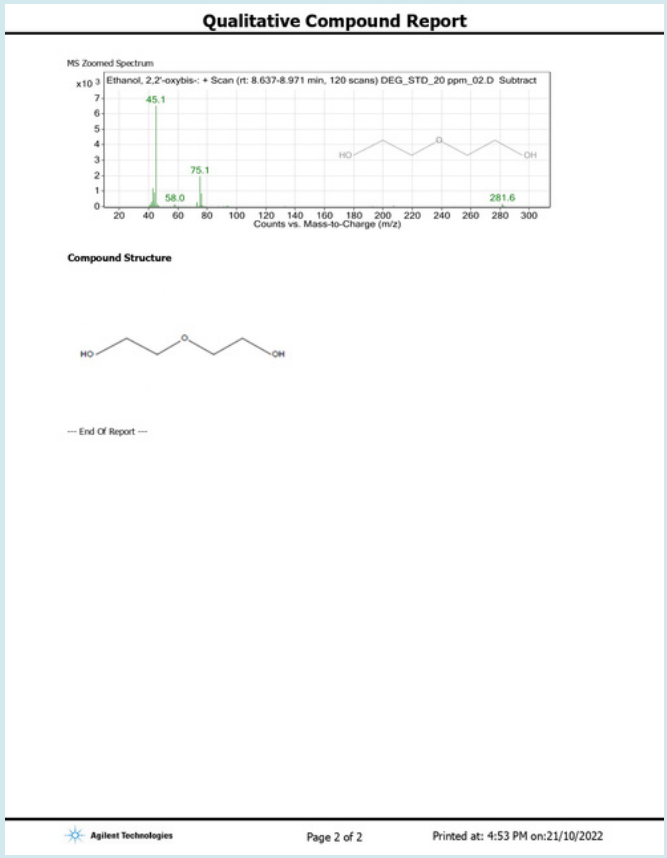
Fragmentor Voltage Collision Energy 0 Ionization Mode Unspecified

Compound Table

Compound Label	Name
Cpd 1: Ethanol, 2,2'-oxybis-	Ethanol, 2,2'-oxybis-

Compound Label	Name	Algorithm
Cpd 1: Ethanol, 2,2'-oxybis-	**Ethanol, 2,2'-oxybis-**	Spectrum Extraction

Agilent Technologies Page 1 of 2 Printed at: 4:53 PM on:21/10/2022



Qualitative Compound Report

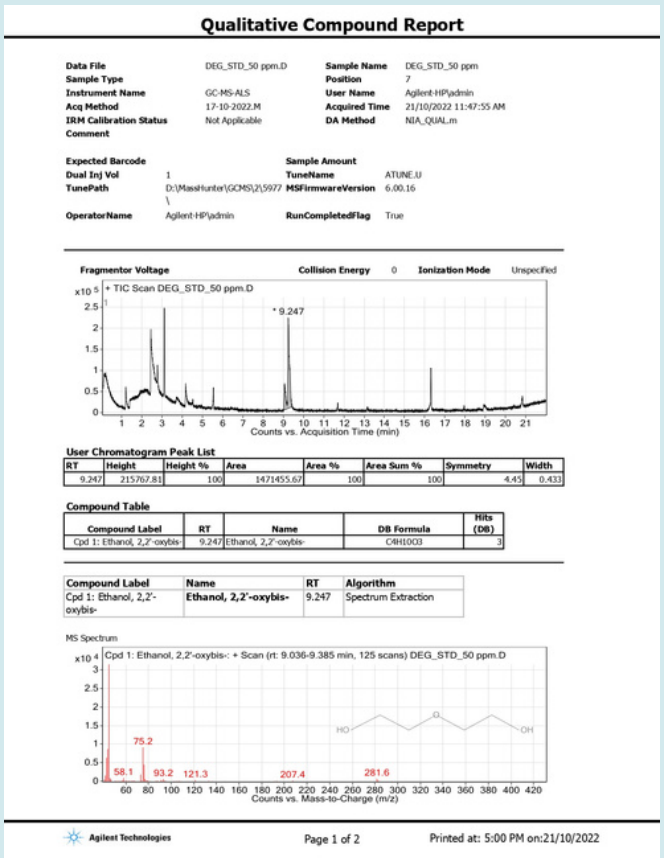
MS Zoomed Spectrum

Compound Structure

--- End Of Report ---

Agilent Technologies Page 2 of 2 Printed at: 4:53 PM on:21/10/2022

DEG Standard (20 ppm)



Qualitative Compound Report

Data File DEG_STD_50 ppm.D
Sample Name DEG_STD_50 ppm
Sample Type
Position 7
Instrument Name GC-MS-ALS
User Name Agilent-HP\admin
Acq Method 17-10-2022.M
Acquired Time 21/10/2022 11:47:55 AM
IRM Calibration Status Not Applicable
DA Method NIA_QUAL.m
Comment

Expected Barcode
Sample Amount
Dual Inj Vol 1
TuneName ATUNE.U
TunePath D:\MassHunter\GCMS\2\5977 \
MSFirmwareVersion 6.00.16
OperatorName Agilent-HP\admin
RunCompletedFlag True

Fragmentor Voltage Collision Energy 0 Ionization Mode Unspecified

User Chromatogram Peak List

RT	Height	Height %	Area	Area %	Area Sum %	Symmetry	Width
9.247	215767.81	100	1471455.67	100	100	4.45	0.433

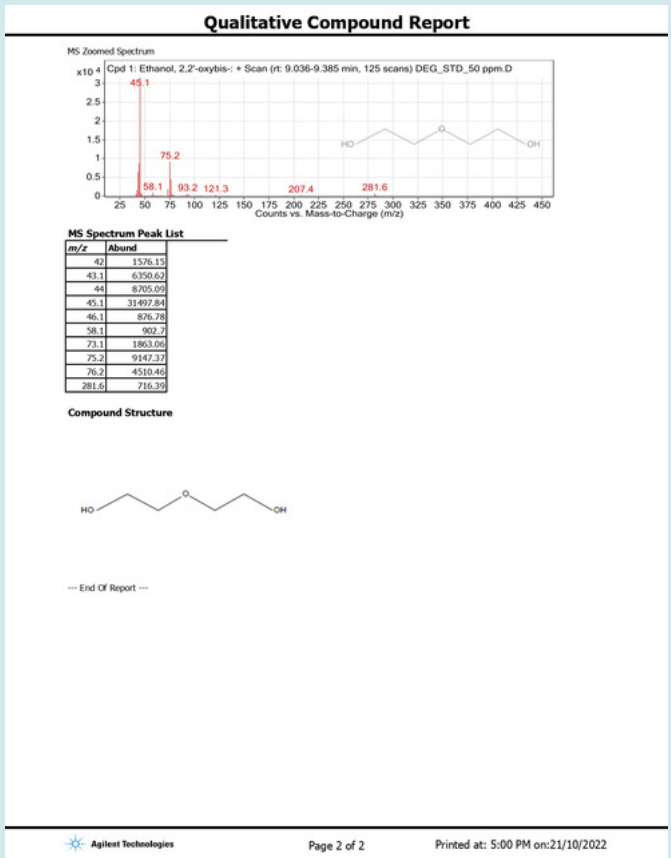
Compound Table

Compound Label	RT	Name	DB Formula	Hits (DB)
Cpd 1: Ethanol, 2,2'-oxybis-	9.247	Ethanol, 2,2'-oxybis-	C4H10O3	3

Compound Label	Name	RT	Algorithm
Cpd 1: Ethanol, 2,2'-oxybis-	**Ethanol, 2,2'-oxybis-**	9.247	Spectrum Extraction

MS Spectrum

Agilent Technologies Page 1 of 2 Printed at: 5:00 PM on:21/10/2022



Qualitative Compound Report

MS Zoomed Spectrum

MS Spectrum Peak List

m/z	Abund
42	1576.15
43.1	6350.62
44	8705.09
45.1	31497.84
46.1	876.78
58.1	902.7
73.1	1863.06
75.2	9147.37
76.2	4510.46
281.6	716.39

Compound Structure

--- End Of Report ---

Agilent Technologies Page 2 of 2 Printed at: 5:00 PM on:21/10/2022

DEG Standard (50 ppm)

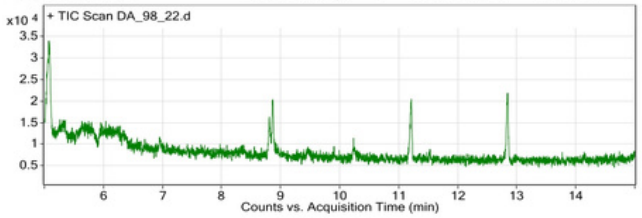
Analysis of Diethylene Glycol / GCMS

Qualitative Compound Report

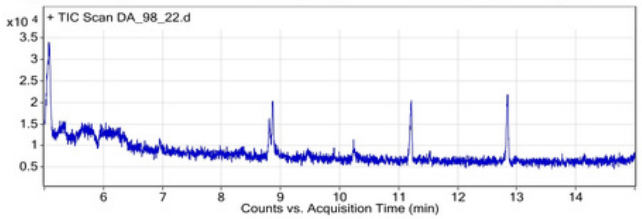
Data File	DA_98_22.D	**Sample Name**	DA_98_22
Sample Type		**Position**	5
Instrument Name	GC-MS-ALS	**User Name**	Agilent-HP\admin
Acq Method	DEG.M	**Acquired Time**	21/10/2022 3:59:18 PM
IRM Calibration Status	Not Applicable	**DA Method**	Default.m
Comment			

Expected Barcode		**Sample Amount**	
Dual Inj Vol	1	**TuneName**	ATUNE.U
TunePath	D:\MassHunter\GCMS\2\5977\	**MSFirmwareVersion**	6.00.16
OperatorName	Agilent-HP\admin	**RunCompletedFlag**	True

Fragmentor Voltage **Collision Energy** 0 **Ionization Mode** Unspecified



Fragmentor Voltage **Collision Energy** 0 **Ionization Mode** Unspecified



Compound Table

--- End Of Report ---

Agilent Technologies Page 1 of 1 Printed at: 4:54 PM on:21/10/2022

DEG Report - DCP Anhydrous

Canberra Chemicals wishes all the readers

Happy Diwali

The END