`

A A

Instrument/User Details

Instrument:	FUSION
User:	QPackSA
Date:	2025/03/18 11:09

A A

Benchmark Tests

Display Colors	**Status**	**Result**
Yellow	Completed	Pass
Blue	Completed	Pass
Green	Completed	Pass
Cyan	Completed	Pass
Red	Completed	Pass
Violet	Completed	Pass
White	Completed	Pass
Clear(off)	Completed	Pass
Beeper	**Status**	**Result**
beeper(on)	Completed	Pass
Motors	**Status**	**Result**
Home Motors	Completed	Pass
Needle Down	Completed	Pass
Needle Up	Completed	Pass
Arm Position A	Completed	Pass
Arm Position 30	Completed	Pass
Carrousel Move Position 5	Completed	Pass
Carrousel Move Position 12	Completed	Pass
Carrousel Move Position 8	Completed	Pass
Solenoid Valves	**Status**	**Result**
Valve no. A	Completed	Pass
Valve no. B	Completed	Pass
Valve no. C	Completed	Pass
Valve no. D	Completed	Pass
Valve no. E	Completed	Pass
Valve no. F	Completed	Pass
Valve no. G	Completed	Pass
Valve no. H	Completed	Pass
Detector	**Status**	**Result**
Detector Readings	Completed	Pass
Door Sensor	**Status**	**Result**
Door(Open/Close)	Completed	Pass
Mass Flow	**Status**	**Result**
Pressure Reading	Completed	Pass
Flow Reading	Completed	Pass
Pumper	**Status**	**Result**
Pumper Valve Pos A	Completed	Pass
Pumper Valve Pos B	Completed	Pass
Pumper Valve Pos C	Completed	Pass
Pumper Valve Pos D	Completed	Pass
Pumper Valve Pos F	Completed	Pass
Pumper Valve Pos G	Completed	Pass
Pumper Valve Pos H	Completed	Pass
Syringe Midrange(12ml)	Completed	Pass
Syringe Max(25ml)	Completed	Pass
Syringe Min(0ml)	Completed	Pass
LeakCheck	**Status**	**Result**
UV LeakCheck	Completed	Pass
IC LeakCheck	Completed	Pass

Blanks

Version: 196
Instrument: FUSION
Last Saved by: QPack Soluções Analíticas Ltda (QPackSA)
Last Saved on: 2025/03/18 13:44 - terça-feira

Acid Count: -0,221
Reagent Count: 5,1173
DI IC Count: 0
DI OC Count: 0
DI TC Count: 0
Comment:

Fusion Report - Água Reagente - 18.03.2025 terça-feira, 18 de março de 2025 02:44

(View - Reps, Unused Reps, Meta-Data, Signature, History)
Printed on 2025/03/18 15:00 - terça-feira

Report Summary Information

Company Location:	LAB		
Schedule Name:	Água Reagente - 18.03.2025	Engine Version:	1.1.5.2
Instrument Name:	FUSION	Firmware Version:	1.2.0701
Report Version:	1 of 1	Connection:	TCP/IP: 172.16.89.116
Report Creation by Operators (schedule version):	QPack Soluções Analíticas Ltda (QPackSA) (v1)		
Comment:			

Report Results

Sample Type: Sample — From Schedule Version 1

	Pos	Analysis Type	Sample ID	Result (ppmC)	Std. Dev. (ppmC)	RSD	Start Time
◈	1	TOC	Água Reagente	0.0533 ppm	0.0000 ppm	0.0000%	2025/03/18 14:44

Rep #	Base Analysis Type	ppm	µg	Adjusted (Abs)	NDIR (Abs)	Baseline (Abs)	Pressure (psig)	Run Time
1	TOC	0.0533	0.2130	7.23	15.50	8.28	49.98	06:19

Dilution	Blank Contribution	Method	Calibration
1:1	(TC) 4.0939 (IC) (v196)	Calibração_2025 (v3)	Calibração 2025 (v2)

Meta Data Used in this Report

Blanks

Version	Reagent (Abs)	Acid (Abs)	DI IC (Abs)	DI TC (Abs)	DI TOC (Abs)	Save Time	Operator
v196	5.1173	-0.2210	0.0000	0.0000	0.0000	2025/03/18 13:44	QPack Soluções Analíticas Ltda (QPackSA)

Calibrations

Name: Calibração 2025 (TOC)

Version:	v2	Calibration curve formula:	TOC: y = 58.798x + 1.545

Ver Creation:	2025/01/21 15:24	r^2 value:	TOC: r^2 = 0.99998
Comment:			
Operator:	QPack Soluções Analíticas Ltda (QPackSA)		
Basic Analysis Type	TOC		

Basic Analysis Type: TOC

Sample ID	Y Raw Value	X Expected	Message	End Time
0.050 ppm	4.4120	0.0500		2007/05/16 22:12
0.100 ppm	7.0520	0.1000		2007/05/16 22:26
0.250 ppm	16.2020	0.2500		2007/05/16 22:40
0.500 ppm	30.6920	0.5000		2007/05/16 22:54
1.000 ppm	61.2220	1.0000		2007/05/16 23:08
5.000 ppm	295.3920	5.0000		2007/05/16 23:22

Methods

Name: Calibração_2025 (TOC)

Version:	v3	Operator:	QPack Soluções Analíticas Ltda (QPackSA)
Ver Creation:	2025/03/18 14:15		
Comment:	This method is designed to use the Non-Purgeable Organic Carbon (NPOC) method for TOC analysis on pharmaceutical type samples, such as water for injection (WFI), purified water and cleaning validation samples. The Low Level Filter for the NDIR setting must be set to On for this method.		

Parameter	Value
SampleVolume	4.0 mL
Dilution	1:1
AcidVolume	0.5 ml
ReagentVolume	0.8 ml
UVReactorPrerinse	Off
UVReactorPrerinseVolume	0.0
NumberOfUVReactorPrerinses	1
ICSpargeTime	0.50 mins
DetectorSweepFlow	500 ml/min
PreSpargeTime	0.20 mins
SystemFlow	500 ml/min

Advanced Parameter	Value
NeedleRinseVolume	5.0 ml
VialPrimeVolume	2.0 ml
ICSamplePrimeVolume	2.0 ml
ICSpargeRinseVolume	5.0 ml
BaselineStabilizeTime	1.60 min
DetectorPressureFlow	300 ml/min
SyringeSpeedWaste	10
SyringeSpeedAcid	7
SyringeSpeedReagent	7
SyringeSpeedDIWater	7
NDIRPressurization	50 psig
SyringeSpeedSampleDispense	7
SyringeSpeedSampleAspirate	4
SyringeSpeedUVDispense	7
SyringeSpeedUVAspirate	5
SyringeSpeedICDispense	7
SyringeSpeedICAspirate	5
NDIRPressureStabilize	1.75 min
SampleMixing	Off
SampleMixingCycles	1

SampleMixingVolume	10.0
LowLevelFilterNDIR	Off

Acceptance / Approval

Electronic Signatures

Report Version	User Name	Acceptance	Reason	Date

Report History

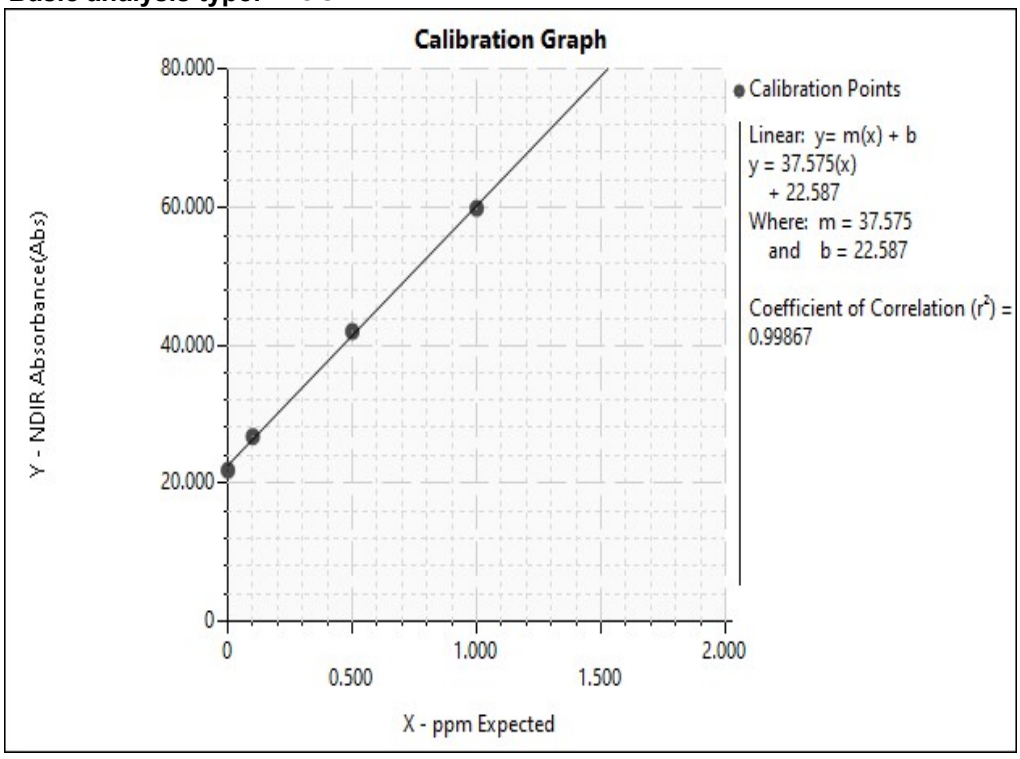
Report History

Report Version	User Name	System Reason	User Reason	Date
1	QPack Soluções Analíticas Ltda (QPackSA)	Schedule completed	Schedule completed	2025/03/18 14:53

Name: Calibração 2025

Analysis Type: TOC
Version: 1
Instrument: FUSION
Last Saved by: QPack Soluções Analíticas Ltda (QPackSA)
Last Saved on: 2025/03/19 10:32 - quarta-feira

Basic analysis type: TOC



Data Points

Sample ID	Y Raw Value	X Expected	Message	End Time
0	21.8920	0.0000		2025/03/19 09:40
0.100 ppm	26.7760	0.1000		2025/03/19 09:50
0.500 ppm	41.9870	0.5000		2025/03/19 09:59
1.000 ppm	59.8120	1.0000		2025/03/19 10:08

Printed on: março 19, 2025 13:24:08

Fusion Report - Check - 19.03.2025 quarta-feira, 19 de março de 2025 03:19

(View - Reps, Unused Reps, Meta-Data, Signature, History)
Printed on 2025/03/19 15:43 - quarta-feira

Report Summary Information

Company Location:	LAB		
Schedule Name:	Check - 19.03.2025	Engine Version:	1.1.5.2
Instrument Name:	FUSION	Firmware Version:	1.2.0701
Report Version:	1 of 1	Connection:	TCP/IP: 172.16.89.116
Report Creation by Operators (schedule version):	QPack Soluções Analíticas Ltda (QPackSA) (v1)		
Comment:			

Report Results

Sample Type: Check Standard --> Check — From Schedule Version 1

	Pos	BAT	Concentration (ppm)	Dil	Sample ID	Min / Max (% dev)	Result	Std. Dev.	RSD	Start Time
◈	1	TOC	0.4000	1:25	[TOC] Check [0.400 ppm]	0.3400 / 0.4600 (85% / 115%)	**0.3757 ppm (PASS)**	0.0000 ppm	0%	2025/03/19 15:19
◈	1	TOC	0.6670	1:15	[TOC] Check [0.667 ppm]	0.5667 / 0.7667 (85% / 115%)	**0.6574 ppm (PASS)**	0.0000 ppm	0%	2025/03/19 15:33

Pos	Base Analysis Type	ID	Rep #	ppm	µg	Adjusted	NDIR	Baseline	Pressure	Run Time
1	TOC	0.400 ppm	1	0.3757	3.3809	36.70	44.30	7.60	49.54	06:55
1	TOC	0.667 ppm	1	0.6574	5.9162	47.29	54.89	7.60	50.00	06:58

Completion State	Success Action	Method	Calibration	STD Conc - Pos 1
Success - Criteria met.	Do Nothing	Calibração 2025 (v1)	Calibração 2025 (v2)	10 ppmC

Meta Data Used in this Report

Blanks

Version	Reagent (Abs)	Acid (Abs)	DI IC (Abs)	DI TC (Abs)	DI TOC (Abs)	Save Time	Operator
v196	5.1173	-0.2210	0.0000	0.0000	0.0000	2025/03/18 13:44	QPack Soluções Analíticas Ltda

							(QPackSA)

Calibrations

Name: Calibração 2025 (TOC)

Version:	v2	Calibration curve formula:	TOC: y = 37.575x + 22.587
Ver Creation:	2025/03/19 13:24	r^2 value:	TOC: r^2 = 0.99867
Comment:			
Operator:	QPack Soluções Analíticas Ltda (QPackSA)		
Basic Analysis Type	TOC		

Basic Analysis Type: TOC

Sample ID	Y Raw Value	X Expected	Message	End Time
0	21.8920	0.0000		2025/03/19 09:40
0.100 ppm	26.7760	0.1000		2025/03/19 09:50
0.500 ppm	41.9870	0.5000		2025/03/19 09:59
1.000 ppm	59.8120	1.0000		2025/03/19 10:08

Methods

Name: Calibração 2025 (TOC)

Version:	v1	Operator:	QPack Soluções Analíticas Ltda (QPackSA)
Ver Creation:	2025/03/19 13:35		
Comment:	This method is designed to use the Non-Purgeable Organic Carbon (NPOC) method for TOC analysis on pharmaceutical type samples, such as water for injection (WFI), purified water and cleaning validation samples. The Low Level Filter for the NDIR setting must be set to On for this method.		

Parameter	Value
SampleVolume	9.0 mL
Dilution	1:1
AcidVolume	0.5 ml
ReagentVolume	0.8 ml
UVReactorPrerinse	Off
UVReactorPrerinseVolume	0.0
NumberOfUVReactorPrerinses	1
ICSpargeTime	0.50 mins
DetectorSweepFlow	500 ml/min
PreSpargeTime	0.20 mins
SystemFlow	500 ml/min

Advanced Parameter	Value
NeedleRinseVolume	5.0 ml
VialPrimeVolume	2.0 ml
ICSamplePrimeVolume	2.0 ml
ICSpargeRinseVolume	5.0 ml
BaselineStabilizeTime	2.00 min
DetectorPressureFlow	300 ml/min
SyringeSpeedWaste	10
SyringeSpeedAcid	7
SyringeSpeedReagent	7
SyringeSpeedDIWater	7
NDIRPressurization	50 psig
SyringeSpeedSampleDispense	7
SyringeSpeedSampleAspirate	4
SyringeSpeedUVDispense	7
SyringeSpeedUVAspirate	5

SyringeSpeedICDispense	7
SyringeSpeedICAspirate	5
NDIRPressureStabilize	2.00 min
SampleMixing	Off
SampleMixingCycles	1
SampleMixingVolume	10.0
LowLevelFilterNDIR	Off

Acceptance / Approval

Electronic Signatures

Report Version	User Name	Acceptance	Reason	Date

Report History

Report History

Report Version	User Name	System Reason	User Reason	Date
1	QPack Soluções Analíticas Ltda (QPackSA)	Schedule completed	Schedule completed	2025/03/19 15:43

Fusion Report - Dilution - 19.03.2025 quarta-feira, 19 de março de 2025 03:50

(View - Reps, Unused Reps, Meta-Data, Signature, History)
Printed on 2025/03/19 16:00 - quarta-feira

Report Summary Information

Company Location:	LAB		
Schedule Name:	Dilution - 19.03.2025	Engine Version:	1.1.5.2
Instrument Name:	FUSION	Firmware Version:	1.2.0701
Report Version:	1 of 1	Connection:	TCP/IP: 172.16.89.116
Report Creation by Operators (schedule version):	QPack Soluções Analíticas Ltda (QPackSA) (v1)		
Comment:			

Report Results

Sample Type: Check Standard --> Dilution — From Schedule Version 1

	Pos	BAT	Concentration (ppm)	Dil	Sample ID	Min / Max (% dev)	Result	Std. Dev.	RSD	Start Time
◈	1	TOC	1.0000	1:10	[TOC] Dilution [1.000 ppm]	0.8500 / 1.1500 (85% / 115%)	**1.0274 ppm (PASS)**	0.0000 ppm	0%	2025/03/19 15:50

Pos	Base Analysis Type	ID	Rep #	ppm	µg	Adjusted	NDIR	Baseline	Pressure	Run Time
1	TOC	1.000 ppm	1	1.0274	9.2466	61.19	68.88	7.69	49.22	06:57

Completion State	Success Action	Method	Calibration	STD Conc - Pos 1
Success - Criteria met.	Do Nothing	Calibração 2025 (v1)	Calibração 2025 (v2)	10 ppmC

Meta Data Used in this Report

Blanks

Version	Reagent (Abs)	Acid (Abs)	DI IC (Abs)	DI TC (Abs)	DI TOC (Abs)	Save Time	Operator
v196	5.1173	-0.2210	0.0000	0.0000	0.0000	2025/03/18 13:44	QPack Soluções Analíticas Ltda (QPackSA)

Calibrations

Name: Calibração 2025 (TOC)

Version:	v2	Calibration curve formula:	TOC: y = 37.575x + 22.587
Ver Creation:	2025/03/19 13:24	r^2 value:	TOC: r^2 = 0.99867
Comment:			
Operator:	QPack Soluções Analíticas Ltda (QPackSA)		
Basic Analysis Type	TOC		

Basic Analysis Type: TOC

Sample ID	Y Raw Value	X Expected	Message	End Time
0	21.8920	0.0000		2025/03/19 09:40
0.100 ppm	26.7760	0.1000		2025/03/19 09:50
0.500 ppm	41.9870	0.5000		2025/03/19 09:59
1.000 ppm	59.8120	1.0000		2025/03/19 10:08

Methods

Name: Calibração 2025 (TOC)

Version:	v1	Operator:	QPack Soluções Analíticas Ltda (QPackSA)
Ver Creation:	2025/03/19 13:35		
Comment:	This method is designed to use the Non-Purgeable Organic Carbon (NPOC) method for TOC analysis on pharmaceutical type samples, such as water for injection (WFI), purified water and cleaning validation samples. The Low Level Filter for the NDIR setting must be set to On for this method.		

Parameter	Value
SampleVolume	9.0 mL
Dilution	1:1
AcidVolume	0.5 ml
ReagentVolume	0.8 ml
UVReactorPrerinse	Off
UVReactorPrerinseVolume	0.0
NumberOfUVReactorPrerinses	1
ICSpargeTime	0.50 mins
DetectorSweepFlow	500 ml/min
PreSpargeTime	0.20 mins
SystemFlow	500 ml/min

Advanced Parameter	Value
NeedleRinseVolume	5.0 ml
VialPrimeVolume	2.0 ml
ICSamplePrimeVolume	2.0 ml
ICSpargeRinseVolume	5.0 ml
BaselineStabilizeTime	2.00 min
DetectorPressureFlow	300 ml/min
SyringeSpeedWaste	10
SyringeSpeedAcid	7
SyringeSpeedReagent	7
SyringeSpeedDIWater	7
NDIRPressurization	50 psig
SyringeSpeedSampleDispense	7
SyringeSpeedSampleAspirate	4
SyringeSpeedUVDispense	7
SyringeSpeedUVAspirate	5
SyringeSpeedICDispense	7
SyringeSpeedICAspirate	5
NDIRPressureStabilize	2.00 min
SampleMixing	Off
SampleMixingCycles	1
SampleMixingVolume	10.0

LowLevelFilterNDIR	Off

Acceptance / Approval

Electronic Signatures

Report Version	User Name	Acceptance	Reason	Date

Report History

Report History

Report Version	User Name	System Reason	User Reason	Date
1	QPack Soluções Analíticas Ltda (QPackSA)	Schedule completed	Schedule completed	2025/03/19 16:00

Fusion Report - System - 19.03.2025 quarta-feira, 19 de março de 2025 04:58

(View - Reps, Unused Reps, Meta-Data, Signature, History)
Printed on 2025/03/19 17:29 - quarta-feira

Report Summary Information

Company Location:	LAB		
Schedule Name:	System - 19.03.2025	Engine Version:	1.1.5.2
Instrument Name:	FUSION	Firmware Version:	1.2.0701
Report Version:	1 of 1	Connection:	TCP/IP: 172.16.89.116
Report Creation by Operators (schedule version):	QPack Soluções Analíticas Ltda (QPackSA) (v1)		
Comment:			

Report Results

Sample Type: System Suitability — From Schedule Version 1

	Pos	System Suitability Sample Type	Sample ID	Result	Std. Dev.	RSD	Start Time
◈	1	Reagent Water	[ReagentWater] System Suitability [Reagent Water]	**0.0377 ppm (PASS)**	0.0000 ppm	0%	2025/03/19 16:58
◈	2	Standard Solution	[StandardSolution] System Suitability [Sucrose (500 ppb)]	0.5865 ppm	0.0000 ppm	0%	2025/03/19 17:08
◈	3	Suitability Solution	[SuitabilitySolution] System Suitability [1,4-Benzoquinone (500 ppb)]	0.5397 ppm	0.0000 ppm	0%	2025/03/19 17:18

Response Efficiency: NaN% — Limit Response (Ru): NaN ppb

(Acceptance Criteria 85% to 115%)

Pos	Rep #	ppm	µg	Adjusted	NDIR	Baseline	Pressure	Run Time
1	1	0.0377	0.3392	5.51	13.17	7.66	50.37	07:05
2	1	0.5865	5.2789	26.13	33.72	7.58	49.68	06:59
3	1	0.5397	4.8576	24.37	32.11	7.74	49.54	06:55

Completion State	Dilution	Blank Contribution	Method	Calibration
Success - All Update Conditions met	1:1	4.0939 (v196)	Calibração 2025 (v1)	Calibração 2025 (v2)

Meta Data Used in this Report

Blanks

Version	Reagent (Abs)	Acid (Abs)	DI IC (Abs)	DI TC (Abs)	DI TOC (Abs)	Save Time	Operator
v196	5.1173	-0.2210	0.0000	0.0000	0.0000	2025/03/18 13:44	QPack Soluções Analíticas Ltda (QPackSA)

Calibrations

Name: Calibração 2025 (TOC)

Version:	v2	Calibration curve formula:	TOC: y = 37.575x + 22.587
Ver Creation:	2025/03/19 13:24	r^2 value:	TOC: r^2 = 0.99867
Comment:			
Operator:	QPack Soluções Analíticas Ltda (QPackSA)		
Basic Analysis Type	TOC		

Basic Analysis Type: TOC

Sample ID	Y Raw Value	X Expected	Message	End Time
0	21.8920	0.0000		2025/03/19 09:40
0.100 ppm	26.7760	0.1000		2025/03/19 09:50
0.500 ppm	41.9870	0.5000		2025/03/19 09:59
1.000 ppm	59.8120	1.0000		2025/03/19 10:08

Methods

Name: Calibração 2025 (TOC)

Version:	v1	Operator:	QPack Soluções Analíticas Ltda (QPackSA)
Ver Creation:	2025/03/19 13:35		
Comment:	This method is designed to use the Non-Purgeable Organic Carbon (NPOC) method for TOC analysis on pharmaceutical type samples, such as water for injection (WFI), purified water and cleaning validation samples. The Low Level Filter for the NDIR setting must be set to On for this method.		

Parameter	Value
SampleVolume	9.0 mL
Dilution	1:1
AcidVolume	0.5 ml
ReagentVolume	0.8 ml
UVReactorPrerinse	Off
UVReactorPrerinseVolume	0.0
NumberOfUVReactorPrerinses	1
ICSpargeTime	0.50 mins
DetectorSweepFlow	500 ml/min
PreSpargeTime	0.20 mins
SystemFlow	500 ml/min

Advanced Parameter	Value
NeedleRinseVolume	5.0 ml
VialPrimeVolume	2.0 ml
ICSamplePrimeVolume	2.0 ml
ICSpargeRinseVolume	5.0 ml
BaselineStabilizeTime	2.00 min
DetectorPressureFlow	300 ml/min
SyringeSpeedWaste	10
SyringeSpeedAcid	7
SyringeSpeedReagent	7
SyringeSpeedDIWater	7
NDIRPressurization	50 psig

SyringeSpeedSampleDispense	7
SyringeSpeedSampleAspirate	4
SyringeSpeedUVDispense	7
SyringeSpeedUVAspirate	5
SyringeSpeedICDispense	7
SyringeSpeedICAspirate	5
NDIRPressureStabilize	2.00 min
SampleMixing	Off
SampleMixingCycles	1
SampleMixingVolume	10.0
LowLevelFilterNDIR	Off

Acceptance / Approval

Electronic Signatures

Report Version	User Name	Acceptance	Reason	Date

Report History

Report History

Report Version	User Name	System Reason	User Reason	Date
1	QPack Soluções Analíticas Ltda (QPackSA)	Schedule completed	Schedule completed	2025/03/19 17:28