CHELAB

FR 20.525257.0005

FINAL REPORT N. 20.525257.0005

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VALIDATION OF THE ANALYTICAL PROCEDURE FOR THE DETERMINATION OF ASSAY OF THE ACTIVE SUBSTANCE ETHANOL (CAS 64-17-5) IN THE PRODUCT "PMC-DISINFETTANTE SUPERFICI" BY GC-FID; DETERMINATION OF ASSAY, CHEMICAL-PHYSICAL AND TECHNICAL PROPERTIES BEFORE AND AFTER AN ACCELERATED STABILITY STUDY AT 54°C FOR 14 DAYS.

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Test Facility:
CHELAB S.r.l.
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31023 Resana (TV)
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Study Director: *Laura Zampieri*

Date:

- Starting date: 07/09/2020
- Experimental phase starting date: 07/09/2020
- Experimental phase completion date: 25/09/2020
- Study completion date: 01/10/2020

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COMPLIANCE STATEMENT

This study was performed by Chelab GLP test facility under my direction (undersigned), according to the Study Plan 20.525257.0005, in compliance with Good Laboratory Practices principles reported in Italian Legislative Decree No. 50 dated March 2, 2007, in adoption of Directive 2004/10/EC.

The results of this report completely and faithfully reflect the raw data generated by the Study.

Date: 04/10/2026

The Study Director

(*Laura Zampieri*)

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QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit has conducted the following inspections and submitted written reports to the to the Study Director and to the Test Facility Management in compliance with the Good Laboratory Practice Principles and Regulations and in accordance with Italian Decree law No. 50 of 2nd March 2007.

Type of inspection	Date of inspection	Inspector	Date reported to a:	
			Study Director	Test Facility Management
Verification of the Study Plan and of the analytical procedure applied	07/09/2020	G. BAZZA	07/09/2020	07/09/2020
Inspection of the analytical phase				
Verification of the Study Report, raw data and compliance to the Study Plan and analytical procedure adopted	01/10/2020	G. BAZZA	01/10/2020	01/10/2020

Date: 01/10/2020

Quality Assurance

(*Giorgia Bazza*)

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1.PURPOSE AND EXPERIMENTAL DESIGN FOR STUDY EXECUTION

Short term study for the validation of the analytical procedure, internally developed and codified as SOPa-LABCHI-79 for the determination of the assay of the active substance Ethanol (CAS 64-17-5) in the disinfectant topic product "PMC-Disinfettante superfici".

The determination of stability of the test item was performed according to CIPAC MT 46.3 (HB O) "Accelerated storage procedure", storing the test item at 54 °C for 14 days.

In particular, the following tests were performed on the test item not subjected to accelerated stability study (t0):

- Assay of active substance
- Appearance (visual inspection)
- Reactivity towards container material (visual inspection)
- Density (liquids, EC method A.3 based on OECD Test Guideline No.109)
- pH (CIPAC MT 75.3, HB J)

The following test were performed on the test item subjected to accelerated stability study for 14 days at 54 °C (t14):

- Assay of active substance
- Appearance (visual inspection)
- Reactivity towards container material (visual inspection and weight change AP-LABCHI-348 rev.1)
- Density (liquids, EC method A.3 based on OECD Test Guideline No.109)
- pH (CIPAC MT 75.3, HB J)

2.INFORMATION ON THE ITEM

2.1.Test Item

Name: PMC Disinfettante superfici

Batch: 200728_01

Manufacturing date: 03/08/2020

Expiry date: 03/08/2022

Receiving date: 05/08/2020

Chelab ID: 20.525257.0005

Description and usage: sanitizing solution for surfaces disinfection, PT2

The declared content of denatured Ethanol in the sample is 75 % w/w (see composition in Annex 1 to the Study Plan) that means 70.4 % w/w of pure Ethanol[1] in the sample.

The tolerance interval of pure Ethanol in the sample is 67.9 – 72.9 % w/w.

Packaging type and appearance of the test item received: 20 glass bottles containing about 100 ml of product.

[1] The alcoholic grade (v/v) of denatured ethanol used for sample formulation is 96 % v/v, corresponding to 93.84 % w/w.

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Storage in the laboratory: in a cool, dry place, away from direct light at room temperature.

2 bottles were stored at 54 °C for 14 days from 08/09/2020 to 22/09/2020 in the climatic chamber SRA 347.

2.2. Placebo

Name: Placebo PMC – Disinfettante superfici

Batch: 200728_03

Manufacturing date: 28/07/2020

Expiry date: 28/08/2020

Receiving date: 05/08/2020

Packaging type and appearance of the test item received: 2 glass bottles containing about 500 ml of placebo.

Storage in the laboratory: in a cool, dry place, away from direct light at room temperature.

3.ACTIVE SUBSTANCE AND ANALYTE TO BE DETERMINED

IUPAC name: Ethanol

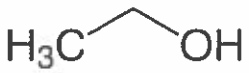
Synonymous: Ethyl Alcohol

CAS nr.: 64-17-5

Molecular Weight: 46.07 g/mol

Molecular Formula: C_2H_6O

Structural Formula:



4.REFERENCE ITEMS

IUPAC name: Ethanol

Synonymous: Ethyl Alcohol

CAS nr.: 64-17-5

Manufacturer: Silcompa S.p.A.

Batch: 2058/200612

Purity: 96.5 % v/v (intended as alcoholic grade, corresponding to 94.57 % w/w[2])

Internal ID: TI-0068074

[2] Value obtained by interpolation of the data reported in EP 01/2018: 50500.

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5.SOPa-LABCHI-79 REV.2 ETHANOL QUANTIFICATION BY GC-FID

The analytical procedure for the quantification of the active substance Ethanol in the test item is described in the analytical method codified as SOPa-LABCHI-79 rev.2 "Determination of Ethanol (CAS 64-17-5) and Isopropanol (CAS 67-63-0) in sanitizing products by GC-FID", annexed to the Study Plan.

The validation of the analytical method was performed in terms of specificity, identification, linearity, accuracy and repeatability according to SANCO 3030/99 Rev.5.

5.1. Instruments and Apparatus

- Common laboratory glassware;
- Analytical balance (± 0.1 mg) SRA 917;
- Analytical balance (± 0.01 mg) SRA 768;
- Automatic pipette SRA 848;
- GC-FID (SRA 240, Agilent model 7890) equipped with liquid autosampler;
- Column: DB-624 30m x 0.32 mm x 1.80 µm (ID: GC 190);
- Inlet liner split 4 mm, single taper with deactivated glass wool, P/N 5183-4647.

Instruments were calibrated before use.

5.2. Reagents and Materials

- Tert-butanol, Internal Standard, TI-0015148
- Acetone, TI-0066108

5.3. Solutions

5.3.1. Blank Solution (BS):

Acetone.

5.3.2. Placebo Solution (for Specificity):

1.4026 g of placebo were accurately (± 0.1 mg) weighed into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.3. Test Solution:

About 1.4 g of test item were accurately (± 0.1 mg) weighed into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone. 5 different preparations were performed for repeatability evaluation.

5.3.4. Test Solution without IS:

1.4036 g of test item were accurately (± 0.1 mg) weighed into a 50 ml volumetric flask and diluted to volume with Acetone.

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5.3.5. Reference Solution L1 (Ethanol at 16084 mg/l):

850.4 mg of Ethanol reference standard were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.6. Reference Solution L2 (Ethanol at 17985 mg/l):

950.9 mg of Ethanol reference standard were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.7. Reference Solution L3 (Ethanol at 20070 mg/l):

1061.1 mg of Ethanol reference standard were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.8. Reference Solution L4 (Ethanol at 22022 mg/l):

1164.3 mg of Ethanol reference standard were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.9. Reference Solution L5 (Ethanol at 24081 mg/l):

1273.2 mg of Ethanol reference standard were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone.

5.3.10. Reference Solutions for SST (Ethanol at ~ 20000 mg/l):

About 1 g of Ethanol reference standard was accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1 ml of IS was added and the solution was diluted to volume with Acetone. 2 different preparations were performed for each analytical sequence for SST.

5.3.11. Fortified placebo for accuracy verification:

0.5741 g of placebo were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 0.8355 g of Ethanol reference standard were added; 1 ml of IS was added and the solution was diluted to volume with Acetone.

Total weight of Fortified placebo was about 1.4 g; the % of Ethanol in the fortified placebo corresponds to about 80%.

0.3648 g of placebo were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1.0414 g of Ethanol reference standard were added; 1 ml of IS was added and the solution was diluted to volume with Acetone.

Total weight of Fortified placebo was about 1.4 g; the % of Ethanol in the fortified placebo corresponds to about 100%.

0.1439 g of placebo were accurately weighed (± 0.1 mg) into a 50 ml volumetric flask; 1.2606 g of Ethanol reference standard were added; 1 ml of IS was added and the solution was diluted to volume with Acetone.

Total weight of Fortified placebo was about 1.4 g; the % of Ethanol in the fortified placebo corresponds to about 120%.

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5.4. Instrumental conditions

Column:	DB-624 30 m x 0.32 mm x 1.80 µm
Liner:	Inlet liner split 4 mm, single taper with deactivated glass wool, P/N 5183-4647
Gas carrier:	Helium
Gas carrier flow:	1 ml/min (constant flow)
Injector temperature:	200 °C
Injection volume:	0.5 µl
Detector:	280 °C
Mode:	Split
Split ratio:	1:100
Gradient temperature:	35°C for 2.5 min; to 70°C at 4°C/min; 1 min at 70°C; to 220°C at 30°C/min, hold time 1 min at 220°C (total run time: 18.25 min)

5.5. Data elaboration

The quantification of Ethanol in the test item is performed by Internal Standard method (Ph. Eur. 2.2.26) and calculated using the following formula:

$$C\ (g/100g) = \frac{A_{TS} \times K_{RS1} \times V}{W \times 10000}$$

Where:

A_{TS}	area ratio of the analyte in Test Solution
K_{RS1}	response factor K of RS1 = concentration in mg/l / average area ratio of the 3 injections
V	sample solving volume (50 ml)
W	sample weight (g)
10000	conversion factor from mg/kg to g/100g

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6.SOPa-LABCHI-79 VALIDATION RESULTS FOR ETHANOL DETERMINATION

The analytical method was validated in terms of specificity, identification, linearity, repeatability and accuracy according to SANCO 3030/99 Rev.5 guidelines.

The determination of analyte at t0 was performed on 5 independent preparations of the test solution (repeatability test). Validation analysis and assay quantification were performed on 07/08/2020.

6.1. System Suitability Test (SST)

SST was performed by injecting at the beginning of the analytical sequence Blank Solution, Reference Solution (RS1) in triplicate and a second preparation of Reference Solution (RS2) in singlet.

It was verified that:

- In Blank Solution, no interferences were present at retention time of the analyte (acceptance criterion: any interfering peak ≤ 0.5 % of the analyte peak area in the Reference Solution see figure 1);
- %RSD of the analyte area ratios of n=3 consecutive injections of the Reference Solution RS1 at the beginning of the analytical sequence was NMT 2%;
- %ratio of the response factors (K) of the RS1 (the average area of the 3 consecutive injections at the beginning of the analytical sequence is considered) and RS2, within 98 and 102%.

In the following table, SST results obtained are reported.

Table 1 - System suitability results: RS1 and RS2 (07/08/2020)

	RS1	RS2	K Ratio
determination	**Area ratio**	**Area ratio**	**%**
1	0.806	0.816	---
2	0.806	---	---
3	0.806	---	---
average	0.806	---	---
Std. Dev.	0.000	---	---
%RSD	0.0	---	---
specification	**%RSD ≤ 2**	---	---
Conformity	**PASS**	---	---
Concentration (mg/l)	20056	20062	---
Response factor K	24884	24586	**99**
specification	---	---	**98-102**
Conformity	---	---	**PASS**

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6.2. Specificity

For specificity evaluation, the following solutions were injected: Blank solution, Placebo solution, Reference solution at target concentration, Test solution and Test Solution without IS. For the identification by GC-MS, see chapter 7.

The specificity was demonstrated, by verifying that:

- In the Blank solution and in Placebo solution no interferences were present at retention time of the analytes (see figure 1);
- The retention time of the analyte in the test solution is the same of the retention time of the analyte in the reference standard solution, see figure 1;
- The interference at retention time of IS in the Test Solution without IS is negligible since the peak response is equal to 0.1% respect the response of the IS peak in the RS1 (average area of the 3 injections of the RS1 was considered).

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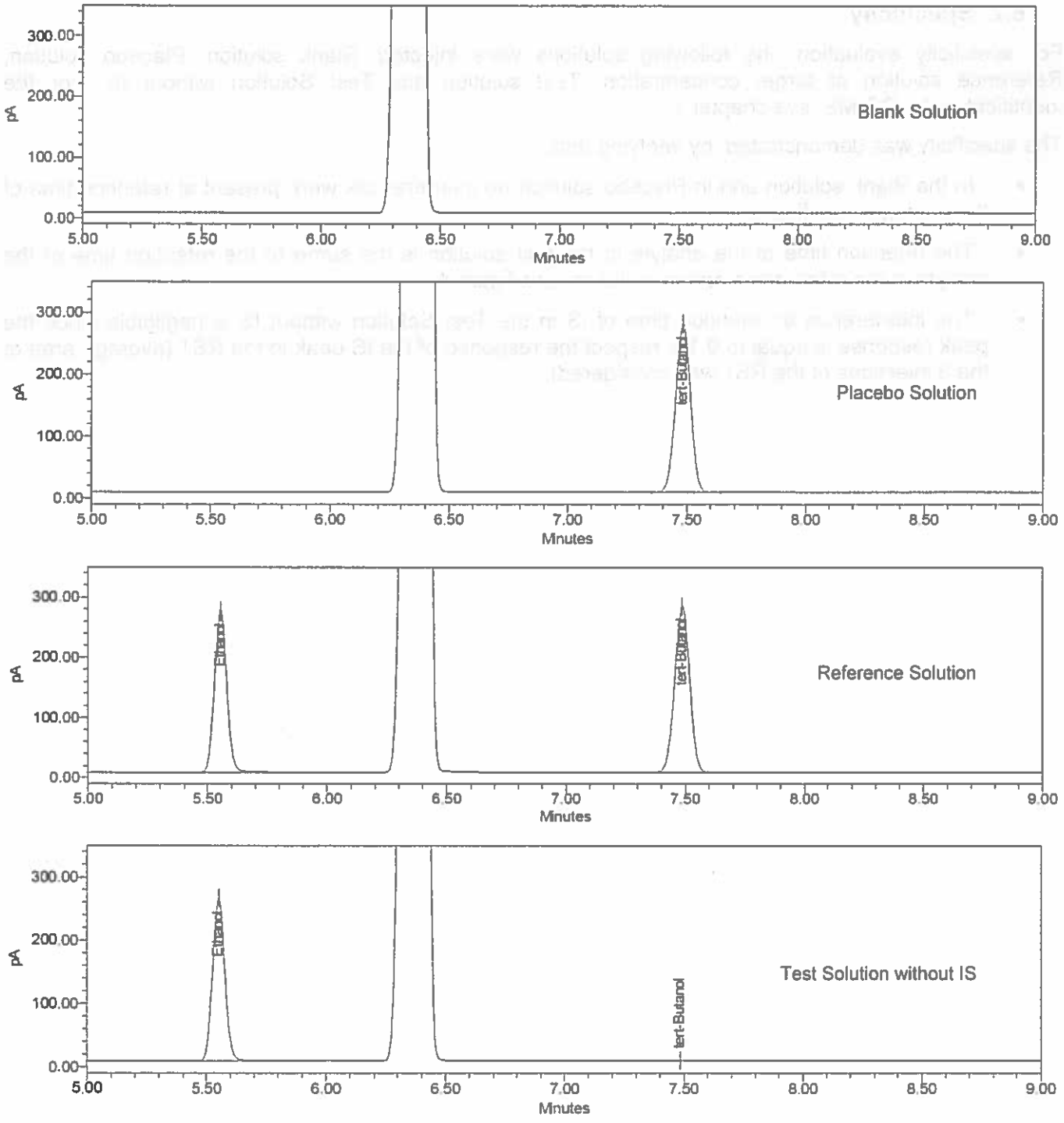

Figure 1 – Blank, Placebo, Reference Solution and Test Solution without IS chromatograms.

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6.3. Linearity

To evaluate linearity, the analysis of 5 Reference Solutions containing the analyte at 5 concentration levels was performed in order to cover the concentration range from at least 80% to 120% of the target concentration.

Using the experimental data of concentration as mg/l (x) and the peak area ratio (y), the equation of the regression curve (y = a + b*x) was calculated.

The obtained results and the statement of conformity to the acceptance criteria defined in the Study Plan are listed below.

Table 2 – Linearity results

ID RS	RS final concent.	% vs target	Conc. in the sample	Area ratio
	mg/l	%	g/100g	
L1	16084	80%	57	0.651
L2	17985	90%	63	0.725
L3	20070	100%	71	0.811
L4	22022	110%	78	0.894
L5	24081	120%	85	0.978

Table 3 – Linearity parameters

Parameter	Result	Specification	Conformity	
Model used	unweighed linear regression (y = a + b*x)	NA	---	---
Slope (b)	0.000041	NA	---	---
Intercept[3] (a)	0	NA	---	---
Visual examination of calibration plot	Random behaviour	NA	---	---
Confidence interval of the intercept	-0.03 - 0.01	Includes 0	Pass ☑	No ☐
Coefficient of correlation (R)	1.00	> 0.99	Pass ☑	No ☐

[3] The intercept (a) can be set equal to 0, since the confidence interval of the intercept includes 0.

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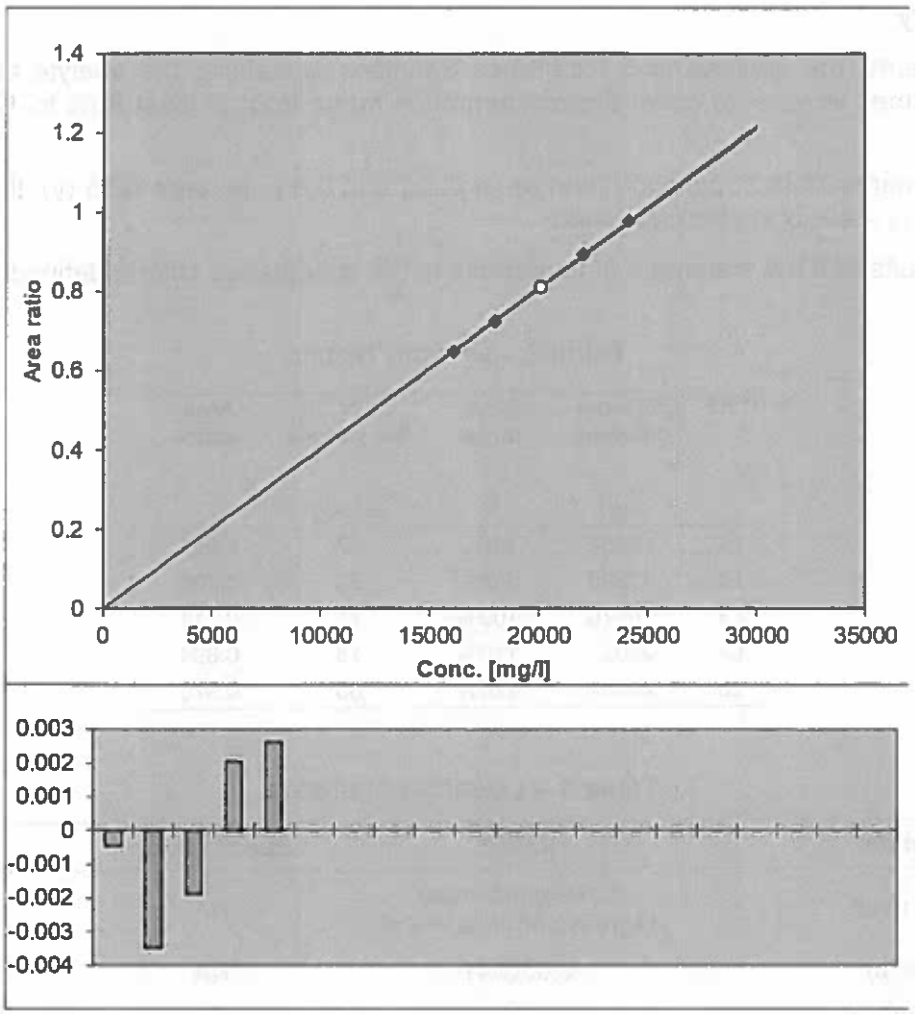

Figure 2 – Linearity regression and residual plots

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6.4. Accuracy

Accuracy evaluation was performed by analysing 3 independent preparations of Placebo fortified with the analyte at 3 concentration levels corresponding to about 80%, 100% and 120% of the target concentration.

Recovery was calculated as follows:

% Recovery = (measured concentration / theoretical concentration) * 100

The results obtained and the statement of conformity to the acceptance criteria defined in the Study Plan are listed below.

Statistical elaboration was done using validated Excel sheets that perform calculation considering all decimal figures. The results included in this document are rounded according to the limits of specification.

Table 4 – Accuracy results

Level	Placebo weight	Ethanol added	Total weight	Theoretical added conc.	% vs target	Solving volume	Area ratio	Measured conc.	Recovery
	g	g	g	g/100g	%	ml		g/100g	%
80%	0.5741	0.8355	1.4096	56.1	80	50	0.646	57.0	102
100%	0.3648	1.0414	1.4062	70.0	99	50	0.808	71.5	102
120%	0.1439	1.2606	1.4045	84.9	121	50	0.976	86.5	102
								Average value	**102**
									Acceptance criteria
								%Rec.	**98-102**
								Conformity	**PASS**

Results are in compliance with the acceptance criterion (recovery between 98% and 102%).

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6.5. Repeatability and assay determination

Repeatability and assay determination were performed on 5 independent preparations of Test Solution of the same test item.

The repeatability result complies with the acceptance criteria defined in the Study Plan corresponding to %RSD (n=5) ≤ 1.4% (Horwitz value).

The results obtained and the statement of conformity to the acceptance criteria are detailed in the following table.

Table 5 – Repeatability and assay results at t0

Replicate	Sample weight	Solving volume	Area ratio	Measured conc. (% w/w)
	g	ml		g/100g
1	1.4035	50	0.808	71.6
2	1.4020	50	0.806	71.5
3	1.4032	50	0.808	71.6
4	1.4044	50	0.808	71.6
5	1.4014	50	0.805	71.5
			average	71.6
			std dev	0.1
			% RSD	0.1
			Acceptance criteria: % RSD ≤ 1.4	
			Acceptance criteria: Pure Ethanol included between 67.9 – 72.9 g/100g	
			Conformity to the Acceptance criteria	**PASS**

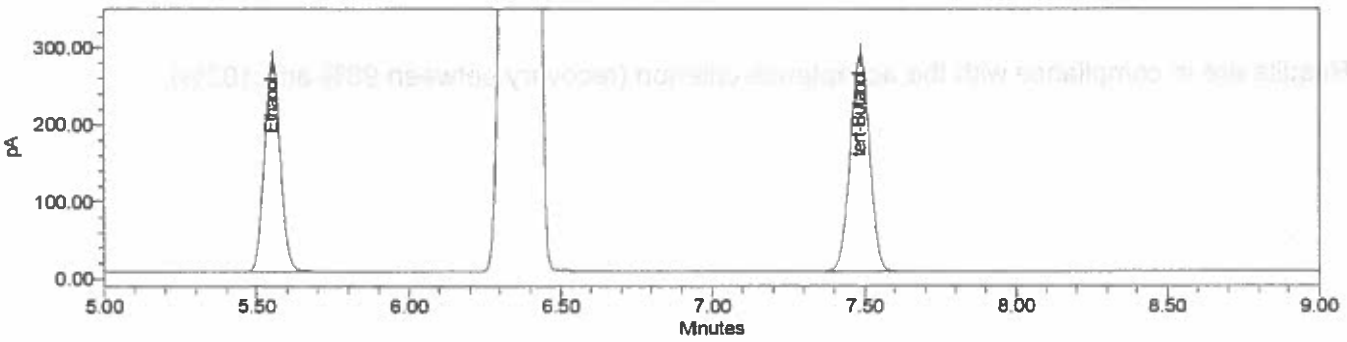

Figure 3 – Representative zoomed chromatogram of Test Solution

Assay measured for the unaged test item t0, obtained from the average of 5 independent analyses, corresponds to 71.6 g/100g (% w/w) of Ethanol in the sample.

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6.6. Analysis of the aged sample

The determination of Ethanol in the aged sample after 14 days at 54 ± 2°C was performed on 24/09/2020 on 3 independent preparations of the Test Solution.

The % variation of assay in the aged sample (t14) respect the unaged sample (t0) was calculated according to the following formula:

$$\%Variation = \frac{|\text{assay in the unaged test item} - \text{assay in the aged test item}|}{\text{assay in the unaged test item}} \times 100$$

For SST, it was verified that:

- In Blank Solution, no interferences were present at retention time of the analyte (acceptance criterion: any interfering peak ≤ 0.5 % of the analyte peak area in the Reference Solution);
- %RSD of the analyte area ratios of n=3 consecutive injections of the Reference Solution RS1 was NMT 2%;
- %ratio of the response factors (K) of the RS1 (the average area of the 3 consecutive injections at the beginning of the analytical sequence is considered) and RS2, within 98 and 102%.

Table 6 – SST results, sequence 24/09/2020 (analysis t14)

	RS1	RS2	K Ratio
determination	**Area ratio**	**Area ratio**	**%**
1	0.771	0.771	---
2	0.771	---	---
3	0.771	---	---
average	0.771	---	---
Std. Dev.	0.000	---	---
%RSD	0.0	---	---
specification	**%RSD ≤ 2**	---	---
Conformity	**PASS**	---	---
Concentration (mg/l)	18923	19022	---
Response factor K	24544	24672	**101**
specification	---	---	**98-102**
Conformity	---	---	**PASS**

The concentration of the analyte in the aged sample t14 and the % variation respect the t0 are reported in the following table.

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As shown, all acceptance criteria were met and the variation of assay of the analyte in the aged sample was lower than 10% respect that obtained at t0.

Table 7 – Assay results for t14

Replicate	Sample weight	Solving volume	Area ratio	Measured conc. (% w/w)
	g	ml		g/100g
1	1.4058	50	0.804	70.2
2	1.4019	50	0.802	70.2
3	1.4065	50	0.805	70.2
			average	70.2
			std dev	0.03
			% RSD	0.04
			%difference vs t0	2
			Acceptance criteria: % RSD ≤ 1.4	
			%difference vs t0 ≤ 10	
			Acceptance criteria: Pure Ethanol included between 67.9 -72.9 g/100g	
			Conformity to the Acceptance criteria	**PASS**

Assay measured for the test item after storage for 14 days at 54°C, obtained from the determination in triplicate, corresponds to 70.2 g/100g (% w/w) of Ethanol in the sample, included in the interval 67.9 and 72.9 g/100g.

No significant difference in terms of assay respect to the unaged sample was observed (absolute %difference = 2).

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7.IDENTIFICATION OF ETHANOL BY GC-MS

Analysis performed on 07/09/2020.

The identification of Ethanol was performed by means of capillary gas chromatography coupled with a mass spectrometer (GC-MS). In this case a GC-MS instrument (SRA 156) was used. The identification was performed by analysis of Test Solution and Reference Solution prepared as described below.
Ethanol analyte in test sample was univocally identified by comparison of MS spectrum with Ethanol spectrum in Reference Solution and with MS spectra library.

7.1. Instruments and Apparatus

- Common laboratory glassware;
- Analytical balance (± 0.1 mg) SRA 768;
- GC-MS (SRA 156) equipped with liquid autosampler;
- 0.45 µm syringe filters;
- Column: DB-624 30m*0.32mm*1.80µm (ID: GC 140).

Instruments were calibrated before use.

7.2. Reagents and Materials

- Acetone, TI-0066109
- Ethanol TI-0068074

7.3. Reference Solutions and Test Solution

7.3.1. Test Solution for GC-MS identification (Ethanol at about 1000 mg/l):

1.4031 mg of test item was accurately (± 0.1 mg) weighed into a 50 ml volumetric flask; then the solution was diluted to volume with Acetone and analysed.

7.3.2. Reference Solution for GC-MS identification (Ethanol at about 1000 mg/l):

1.0077 mg of Ethanol reference standard was accurately weighed (± 0.1 mg) into a 25 ml volumetric flask; then the solution was diluted to volume with Acetone.

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7.4. Instrumental conditions

Column:	DB-624 30 m x 0.32 mm x 1.80 µm
Liner:	Inlet liner split 4 mm, single taper with deactivated glass wool, P/N 5183-4647
Gas carrier:	Helium
Gas carrier flow:	1 ml/min (constant flow)
Injector temperature:	200 °C
Injection volume:	1 µl
Mode:	Split
Split ratio:	1:100
Gradient temperature:	35°C for 2.5 min; to 70°C at 4°C/min; 1 min at 70°C; to 220°C at 30°C/min, hold time 1 min at 220°C (total run time: 18.25 min)

MS parameters:

Full scan m/z range:	20-150
MS Source T:	230 °C
MS Quadrupole T:	150 °C
Detector off:	2.05 min
EMV mode	Gain factor
Gain factor	1.00
Resulting EMVoltage	1129

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7.5. Results

In the following figure, the Total Ion Chromatograms (TIC) and mass spectra of Ethanol peak are reported.

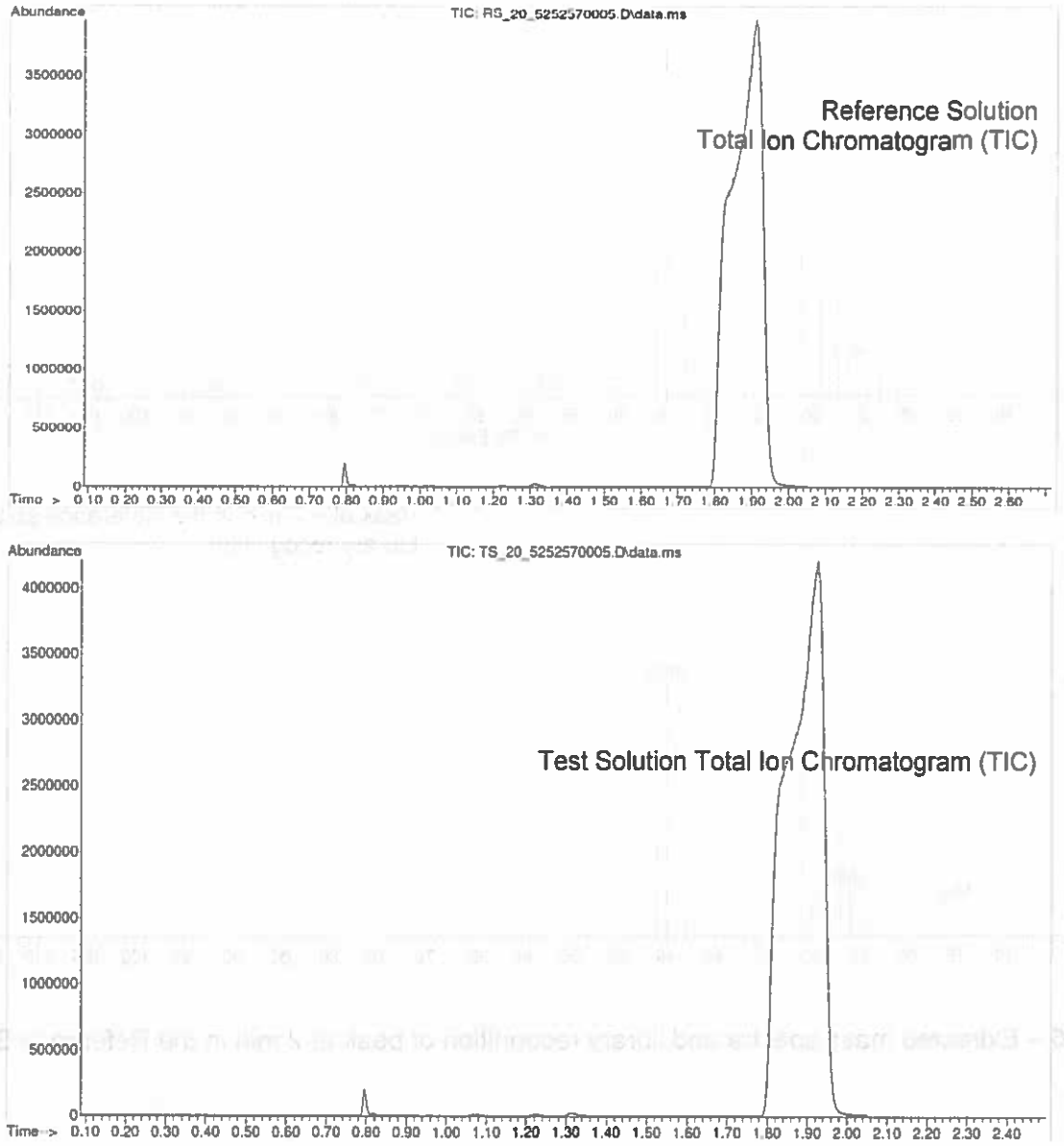

Figure 4 – Total Ion Chromatograms (TIC) of the Reference and Test Solution.

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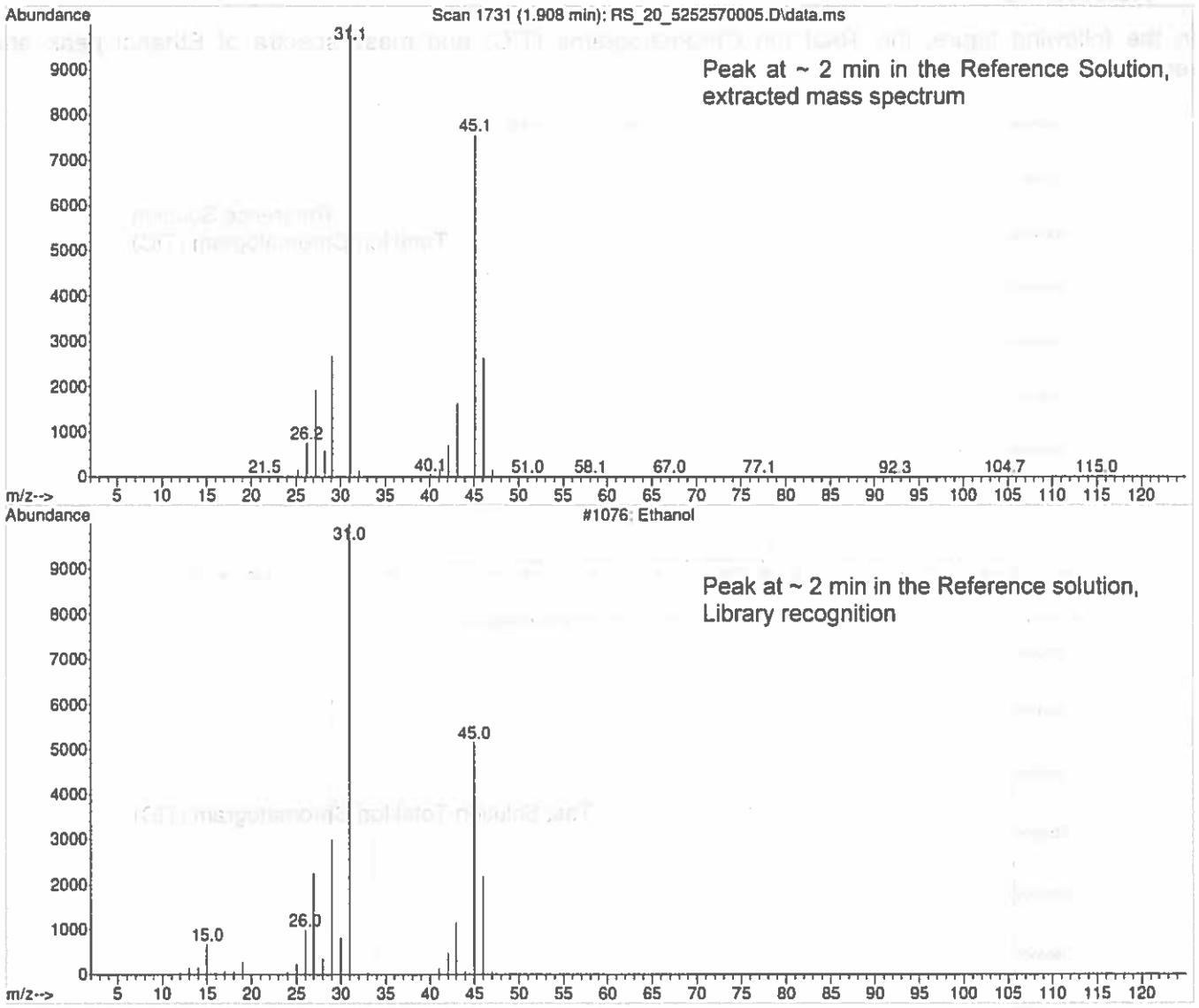

Figure 5 – Extracted mass spectra and library recognition of peak at 2 min in the Reference Solution.

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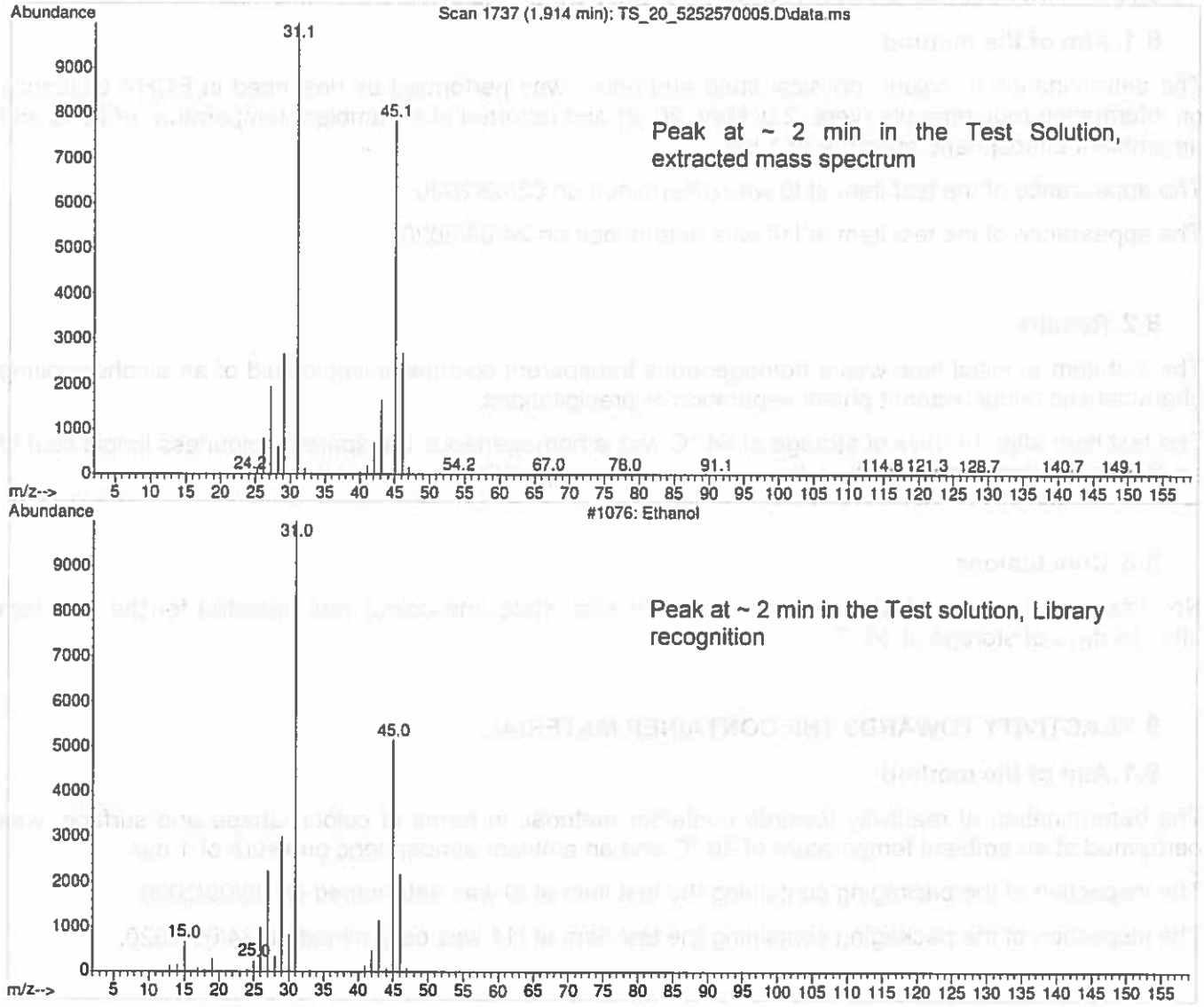

Figure 6 – Extracted mass spectra and library recognition of peak at 2 min in the Test Solution.

The retention time of the peak at ~ 2 min in the Test Solution is the same of that in the Reference Solution; the mass spectrum of the peak in the Test Solution is the same of that in the Reference Solution; moreover the peak has been attributed to Ethanol by the mass library.

Therefore, Ethanol peak is univocally identified in the Test Solution.

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8.APPEARANCE, ODOUR, PHYSICAL STATE AND COLOUR

8.1. Aim of the method

The determination of colour, physical state and odour was performed as described in ECHA Guidance on information requirements (vers. 2.0, May. 2018) and reported at an ambient temperature of 20°C and an ambient atmospheric pressure of 1 bar.

The appearance of the test item at t0 was determined on 08/09/2020.

The appearance of the test item at t14 was determined on 24/09/2020.

8.2. Results

The test item at initial time was a homogeneous transparent colourless limpid fluid of an alcoholic biting characteristic odour, without phase separation or precipitations.

The test item after 14 days of storage at 54 °C was a homogeneous transparent colourless limpid fluid of an alcoholic biting characteristic odour, without phase separation or precipitations.

8.3. Conclusions

No difference in terms of appearance, odour, physical state and colour was detected for the test item after 14 days of storage at 54 °C.

9.REACTIVITY TOWARDS THE CONTAINER MATERIAL

9.1. Aim of the method

The determination of reactivity towards container material, in terms of colour, shape and surface, was performed at an ambient temperature of 20 °C and an ambient atmospheric pressure of 1 bar.

The inspection of the packaging containing the test item at t0 was determined on 08/09/2020.

The inspection of the packaging containing the test item at t14 was determined on 24/09/2020.

9.2. Results

Packaging description at initial time point: glass bottle containing about 100ml of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging.

Packaging description after 14 days at 54 °C: glass bottle containing about 100ml of liquid; no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging.

9.3. Conclusions

No difference in terms of appearance of the container material was detected for the test item after 14 days of storage at 54 °C.

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10. WEIGHT CHANGE

10.1. Aim of the method

The determination of the weight change of the packaging containing the test item was performed according to internal method AP-LABCHI-348 rev.1 after the accelerated storage for 14 days at 54 ± 2 °C.

10.2. Instrument

Technical balance SRA 685.

Instrument was calibrated before use.

10.3. Results

3 bottles were weighed before being introduced in the climatic chamber (t0), SRA 347 (08/09/2020) and at the end (tn) of the accelerated storage 14 days at 54 ± 2 °C (22/09/2020).

The weight change was calculated as follows:

$$\text{Weight change (\%)} = \frac{t0 - tn}{t0} * 100$$

Where:

t_0: initial weight of the packaging containing the unaged sample (g)

t_n: weight of the packaging containing the aged sample (g).

The results are reported in the table below.

Table 8 – Weight change determination

	Weight		Weight change
Bottle	t_0 (g)	t_n (g)	%
1	253.80	253.58	0.1
2	248.97	248.79	0.1
		Average	0.1

10.4. Conclusion

No significant difference in terms of weight change between the test item at t0 and t14.

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11. pH DETERMINATION

11.1. Aim of the method

The aim of the method is the determination of pH of the pure test item at 25 ± 2 °C in accordance to the CIPAC MT 75.3 (HB J) method on the test item at initial time (08/09/2020) and at t14 (24/09/2020).

The pH determination was performed in triplicate on the undiluted test item at t0 and t14.

11.2. Instruments

- Common laboratory glassware;
- Thermostatic bath (SRA 648);
- pH-meter (SRA 597) with accuracy of ± 0.01, equipped with thermometer and automatic correction system of the reading (temperature at which the electrode is working).

Instruments were calibrated before use.

11.3. Results

pH results obtained are reported in the table below.

Table 9 - pH results obtained at t0 and t14

Replicate	t0	t14
1	7.91	7.02
2	7.92	6.95
3	7.89	7.05
average	7.91	7.01
Std. Dev.	0.02	0.05
%RSD	0.2	0.7

11.4. Conclusions

Initial time point: mean pH value at 25 °C is 7.91.

T14: mean pH value at 25 °C is 7.01.

pH is included between 6.50 – 8.50 at at t0 and t14 (see paragraph 14, AMENDMENTS AND/OR DEVIATION FROM THE STUDY PLAN).

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12. DENSITY

12.1. Aim of the method

The aim of the method is the determination of density of the unaged test item (08/09/2020) and aged test item (25/09/2020).

The relative density determination (respect water density at 20 °C) was done according to EC method A.3 (based on OECD Test Guideline No 109) by pycnometric method in triplicate.

12.2. Instruments and materials

- Pycnometer equipped with a thermometer 0 - 40 °C (± 0.1°C) DIN 12809;
- Analytical balance (± 0.1 mg), SRA 917;
- Thermostatic Water bath, SRA 648;
- milliQ water, SRA 692.

Instruments were calibrated before use.

12.3. Results

Water and the test item were equilibrated at 20 °C and the empty pycnometer was weighed (P_0). The pycnometer was filled with water and weighed (P_1) and then filled with test item and weighed (P_2).

At each recording of the different masses, the temperature was visually checked.

The density was calculated as follows, using the density of water at 20 °C (0.9982 g/cm^3):

$$\rho(g/cm^3) = \frac{(P_2 - P_0)_{,20°C}}{(P_1 - P_0)_{,20°C}} \times 0.9982$$

Results obtained are reported in the following table.

Table 10 - Density results at t0.

Analyte:	P_0	P_1	P_2	Density
determination	g	g	g	g/cm^3
1	39.4041	63.5113	60.3790	0.8685
2	39.4041	63.5113	60.3389	0.8668
3	39.4041	63.5113	60.3434	0.8670
			average	0.8675
			Std. Dev.	0.0009
			%RSD	0.1

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Table 11 - Density results at t14.

Analyte:	P_0	P_1	P_2	Density
determination	g	g	g	g/cm^3
1	27.6942	37.5159	36.1680	0.8631
2	27.6942	37.5159	36.2107	0.8656
3	27.6942	37.5159	36.2039	0.8649
			average	0.8645
			Std. Dev.	0.0013
			%RSD	0.1

12.4. Conclusion

Initial time point: mean density value at 20 °C is 0.8675 g/cm^3 (approximated value 0.868 g/cm^3).

T14: mean density value at 20 °C is 0.8645 g/cm^3 (approximated value 0.865 g/cm^3).

Density is included between 0.850 - 0.890 g/ml (or g/cm^3) both at initial time point and both at t14.

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13. CONCLUSIONS

13.1. Validation summary results

The validation of the analytical method SOPa-LABCHI-79 rev.2 was performed in terms of specificity/identification, linearity, accuracy and repeatability according to SANCO 3030/99 Rev.5.

All acceptance criteria were met and no deviations were observed during the execution of this validation, therefore the method is suitable for the determination of Ethanol (CAS 64-17-5) in the disinfectant topic product "PMC-Disinfettante superfici".

Table 12 – Validation summary results

Parameter	Operative Conditions	Acceptance criteria	Results
Specificity (6.2)	Analysis of blank, placebo, reference item and test item solutions.	No interference or interferences from other substances present in the blank and placebo should influence the determination of the analyte (interferences lower than 0.5% vs target concentration). The retention time of the analyte in the test solution has to be the same of the retention time of the analyte in the reference standard solution.	No interferences were observed in placebo and blank solutions at retention times of the analyte/IS. Retention times of analyte/IS peaks in the Reference Solution is equivalent to that of the correspondent peak in the Test Solution. No significant interference of IS in the Test Solution.
Identification (7)	GC-MS SCAN analysis of the Reference and Test Solutions.	The MS spectra of the analyte peak in the Test Solution has to be the same to the Reference Solution (peaks must have also the same retention time).	PASS
Linearity (6.3)	Analysis of 5 reference solutions prepared from at least 80% to 120% of target concentration.	Correlation coefficient (R) should be > 0.99 The confidence interval of the intercept has to include 0	R = 1.00 PASS
Accuracy (6.4)	Analyses of 3 reconstituted samples (placebo spiked with known amount of reference item at the 80%, 100% and 120% of nominal concentration) or 3 independent preparations of placebo spiked with known amount of reference item at 100% of the nominal concentration.	Recovery between 98 and 102%.	%Recovery = 102 PASS
Repeatability / Precision (6.5)	5 independent analyses of test item solution	%RSD (n=5) ≤ 1.4	%RSD = 0.1 PASS

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13.2. Test item characterization and stability results

Stability was evaluated after storage for 14 days at 54°C in terms of assay, aspect, reactivity towards container material, weight change, density and pH.

The test item was stored at 54 °C in the climatic chamber SRA 347 from day 08/09/2020 to the day 22/09/2020.

Stability summary results are reported in the following table.

Table 13 - Summary results

Test	Time point 0	After storage 14 days 54 °C	Comparison vs t0
Assay	71.6% w/w (pure Ethanol)	70.1% w/w (pure Ethanol)	Δ vs t0: 2% Not significant difference
Aspect	Homogeneous transparent colourless limpid fluid of an alcoholic biting characteristic odour, without phase separation or precipitations.	Homogeneous transparent colourless limpid fluid of an alcoholic biting characteristic odour, without phase separation or precipitations.	Not significant difference
Reactivity towards container material	Transparent glass bottle, no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging.	Transparent glass bottle, no sample leaks or signs of deformation, discolouration, foulings, bulges or spots on the packaging.	Not significant difference
Weight change	Bottle 1: 253.80 g Bottle 2: 248.97 g	Bottle 1: 253.58 g Bottle 2: 248.79 g	Δ vs t0: 0.1% Not significant difference
Density (20 °C)	0.8675 g/cm^3	0.865 g/cm^3	-
pH	7.91	7.01	In specification in both cases, even if a difference of 0.90 occurred

The test item can be considered stable after the accelerated storage for 14 days at 54°C.

Moreover the test item resulted in compliance with the acceptance criteria given by the Sponsor at both time points (concentration of pure Ethanol included between 67.9 – 72.9 g/100g).

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14. AMENDMENTS AND/OR DEVIATION FROM THE STUDY PLAN

The guideline "ECHA Guidance on the Biocidal Products Regulation, Volume I, Part A, vers. 1.1, Nov. 2014" is reported in the validation protocol with the wrong revision; the correct version is "ECHA Guidance on the Biocidal Products Regulation (Volume I, Parts A + B + C, vers. 2.0, May 2018)", that is the version used by the analyst.

After communication of preliminary results obtained on sample at t0 and t14 for pH (7.91 at t0 and 7.01 at t14), the Sponsor changed the tolerance interval for pH (from 7.50 – 9.00 to 6.050 – 8.50). See the Sponsor declaration in Annex 1 and the test item certificate containing the new tolerance interval in Annex 2.

15. REFERENCES

- SANCO 3030/99 Rev.5: "Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414"
- CIPAC MT 46.3 HB O method "Accelerated storage procedure"
- ECHA Guidance on the Biocidal Products Regulation (Volume I, Parts A + B + C, vers. 2.0, May 2018)
- SOPa-LABCHI-79 rev.2 "Determination of Ethanol (CAS 64-17-5) and Isopropanol (CAS 67-63-0) in sanitizing products by GC-FID".
- CIPAC MT 75.3 (HB J) method "Determination of pH values"
- AP-LABCHI-348 rev.1 "Analytical Procedure for the determination of weight loss"
- EC method A.3 (2008) and OECD Test Guideline No.109 (2012) "Density of Liquids and Solids"

16. ARCHIVING

Document/Registration	Archiving period
Study Plan original, amendments to the Study Plan, Original Final Report, Method of Analysis, inspection reports, raw data	10 years
Sample of test item	No reserve samples were committed to the Testing Facility by the sponsor
Support materials needed for the study	10 years

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17. ANNEXES AND/OR ATTACHMENTS

Attachment 1: Study Plan

Annex 1: Sponsor declaration

Annex 2: test item certificate containing the new tolerance interval

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Annex 1: Sponsor declaration

RES PHARMA
INNOVATIVE INGREDIENTS

On.le Ministero della Salute
Direzione Generale dei Dispositivi Medici
e del Servizio Farmaceutico
UFFICIO I - Affari generali e prodotti di interesse
sanitario diversi dai dispositivi medici
Via Giorgio Ribotta, 5
00144 – ROMA

Trezzo sull'Adda, 01/10/2020

PT2 PMC - Disinfettante superfici STUDIO BPL FR20.525257.0005

Cambio delle specifiche

A seguito dei dati di stabilità ottenuti nello studio BPL FR20.525257.0005 si è proceduto ad un'ulteriore valutazione delle caratteristiche di tutti gli ingredienti della formulazione "PT2 PMC - Disinfettante superfici", da cui è emerso che il cambiamento del pH non è in alcun modo dovuto a modifiche del principio attivo (etanolo) né è rilevante sia per le caratteristiche di aspetto e funzionalità del prodotto sia per la sicurezza, essendo un valore di pH neutro.

Si è pertanto deciso di modificare il range di specifica di accettazione del pH portandolo ad un range più adatto di "6.50 – 8.50".

Distinti saluti

RES PHARMA INDUSTRIALE S.r.l.
Fabio Angeleri
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CHELAB

FR 20.525257.0005

Annex 2: test item certificate containing the new tolerance interval

RES PHARMA
INNOVATIVE INGREDIENTS

SCHEDA TECNICA

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PMC - Disinfettante superfici

CODICE: PT2 VERSIONE 2 01/10/2020

IDENTIFICAZIONE DEL PRODOTTO

Nome Commerciale: PMC - Disinfettante superfici

Descrizione ed usi: Liquido sanitizzante superfici.

Composizione:

Nome INCI EU (US)	CAS	CE	% p/p
Etanolo	64-17-5	200-578-6	75
Acqua	7732-18-5	231-791-2	q.b a 100
Glicole propilenico	57-55-6	200-338-0	1
Sodio Laurileter Solfato (2 OE)	68891-38-3	500-234-8	1

SPECIFICHE

I parametri riportati nelle Specifiche sono controllati per ogni lotto di produzione. I relativi valori saranno presenti sui certificati di analisi che accompagnano ogni lotto.

PARAMETRO METODO NOTE	U.M.	VALORE DI CAPITOLATO
ASPETTO MP_01		Liquido limpido
DENSITÀ MP_02	g/ml	0,850 - 0,890
pH MP_04		6,50 - 8,50

NOTE

Shelf life: 24 Mesi

Le informazioni contenute in questa scheda si basano sulle nostre migliori conoscenze alla data sopra riportata. L'utilizzatore è comunque tenuto alla verifica dell'idoneità delle stesse in relazione all'utilizzo specifico cui è destinato il prodotto; pertanto, non è possibile assumere in merito alcuna responsabilità diretta o indiretta.

Questa scheda è di proprietà della Res Pharma Industriale e annulla e sostituisce ogni precedente versione.

Dossier Manager