

USER MANUAL for CREATING the ANALYTICAL REQUEST LETTER (Ed. 01)

1. INTRODUCTION and PURPOSE

This manual is intended to explain each step for correctly filling - by REDOX customers - the analytical request letter, both for the pharmaceutical and non-pharmaceutical sectors, by the use of an on-line portal.

Regarding the pharmaceutical sector, particular attention is given to the category of the analysis to be performed, therefore if they are intended for **GMP** or **NON-GMP** purposes.

The use of the portal is **personal** and allows to generate a letter in order to highlight both the analyses to be performed and the analytical methods.

Moreover, in order to minimize transcription errors during the acceptance phase in the LIMS at REDOX, a **QR code** with the name and the batch of the sample is generated (this latter implies a correct correspondence between that the data written in the form and those reported on the samples label).

The personal **history** of all the previous requests is also available.

Three phases are required in order to generate a request letter:

1. **Registration/ First access to the portal**
2. **Fields filling**
3. **Hard copy (print-out) of the request letter**

Some notes:

- The assignment of the analysis as *GMP* or *NON-GMP* could be independent from the field of the *product*: for instance, it can be an API but the analysis can be NON-GMP – i.e. if the method is NOT validated.
- The letter must be always **printed-out on paper** and sent to REDOX with the sample since REDOX cannot access to customers' account.

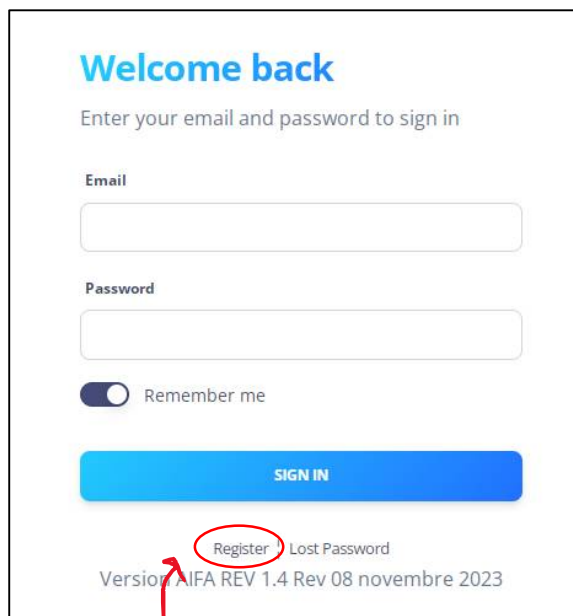
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2. REGISTRATION/FIRST ACCESS

2.1 Registration

Connect to the website <https://sampleplatform.labredox.com/>

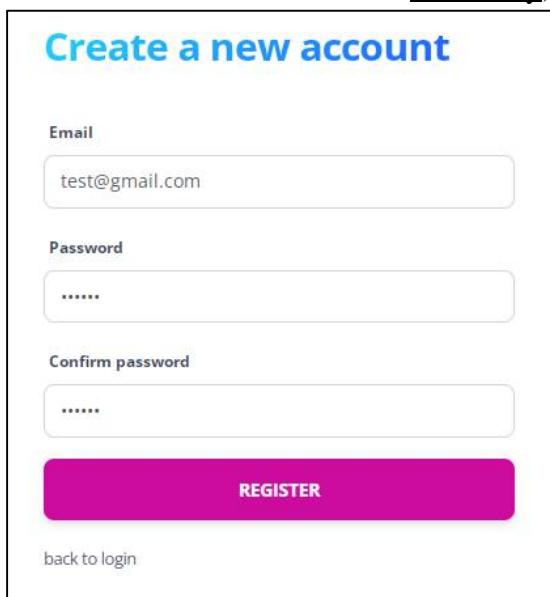


The screenshot shows a login interface with the heading "Welcome back" and the instruction "Enter your email and password to sign in". It includes input fields for "Email" and "Password", a "Remember me" toggle switch, and a blue "SIGN IN" button. Below the button, there are two links: "Register" (circled in red with a red arrow pointing to it) and "Lost Password". At the bottom, the version information "Version AIFA REV 1.4 Rev 08 novembre 2023" is displayed.

Click “Register” and fill out the form with the chosen email and password (at least 6 characters).

Note: The mail address could be cumulative for several people (es: mail address of a department) in order to have the possibility to have a multi access to the portal).

INSERT the chosen mail address accurately, otherwise registration will not be possible.

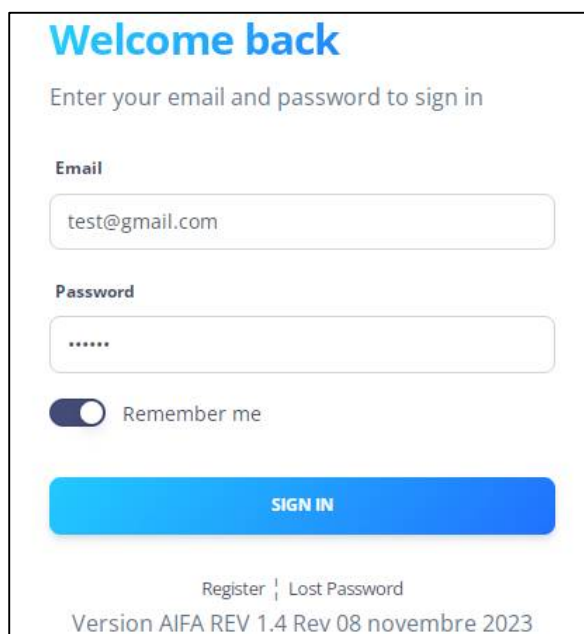


The screenshot shows a registration form with the heading "Create a new account". It includes input fields for "Email" (containing "test@gmail.com"), "Password" (with six dots), and "Confirm password" (with six dots). A pink "REGISTER" button is at the bottom, along with a "back to login" link.

By clicking "Register", after a few seconds a mail with the request of address confirmation is received: by clicking the link therein, the profile is activated and thus automatically reached (in the case of a waiting time exceeding a few minutes, please contact immediately REDOX: the email address may have been incorrectly transcribed or other compatibility issues have occurred (eg.: firewall settings)).

2.2 First access

It's now possible to log into the portal from <https://sampleplatform.labredox.com/>, entering the data provided during the registration and clicking "Sign in".



Welcome back

Enter your email and password to sign in

Email

test@gmail.com

Password

Remember me

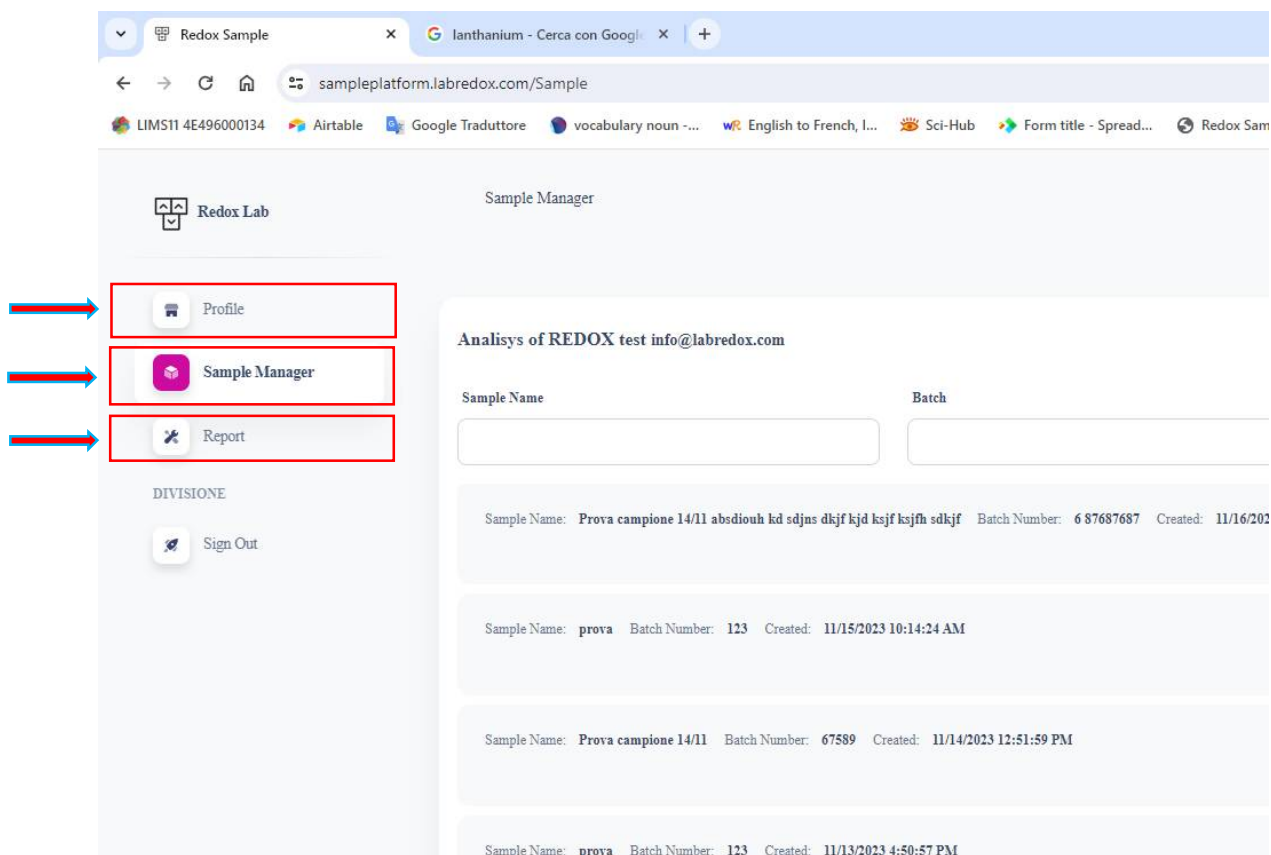
SIGN IN

[Register](#) | [Lost Password](#)

Version AIFA REV 1.4 Rev 08 novembre 2023

The homepage of the portal then appears and three main options are present in the side menu:

- **Profile:** where it's necessary to insert the contact detail information of the applicant, since they will appear on the request letter
- **Sample Manager:** where it's possible to insert new samples to send for analysis
- **Report:** where it's possible to print-out the request letter on paper.



3. FILLING IN THE FIELDS

3.1 Profile

The “e-mail” field (marked in the figure by N°1) corresponds to the registration email and CANNOT be modified (dimmed in grey)

Enter your Name and Surname in the “Name Surname” field (this field is system only – therefore necessary – but will not appear in the documents).

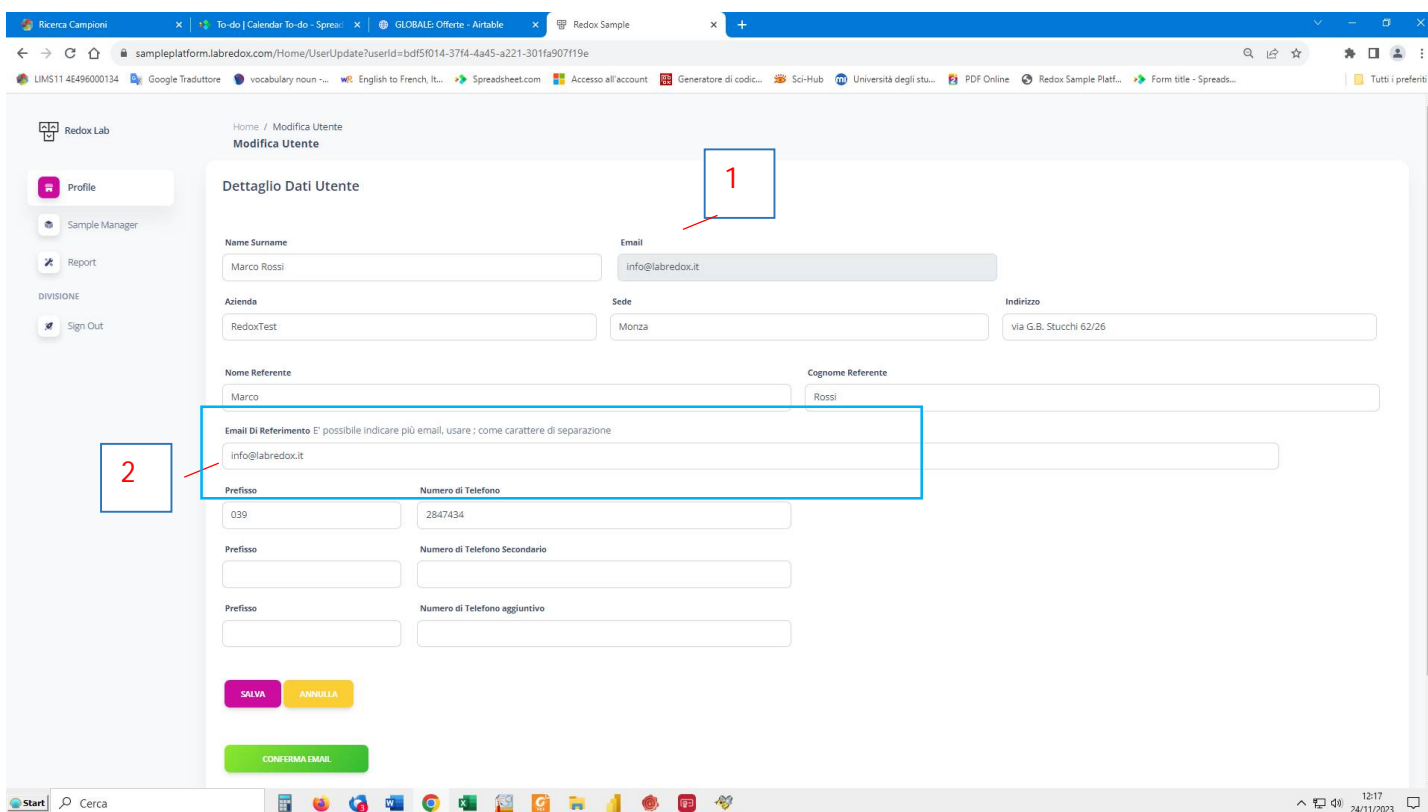
Below, repeat your Name and Surname in the two fields.

Then enter the Company, Site and Address: it’s important to specify the Site especially in the case of companies which have several.

- - Then enter your Name and Surname in the two fields below: these will appear in the request letter.

The "reference email" field (marked in the figure by N°2) is to be used to indicate **all** the mail addresses to which the certificates must be sent (*your own and additional ones*).

Mailboxes must be entered separated by “;”.



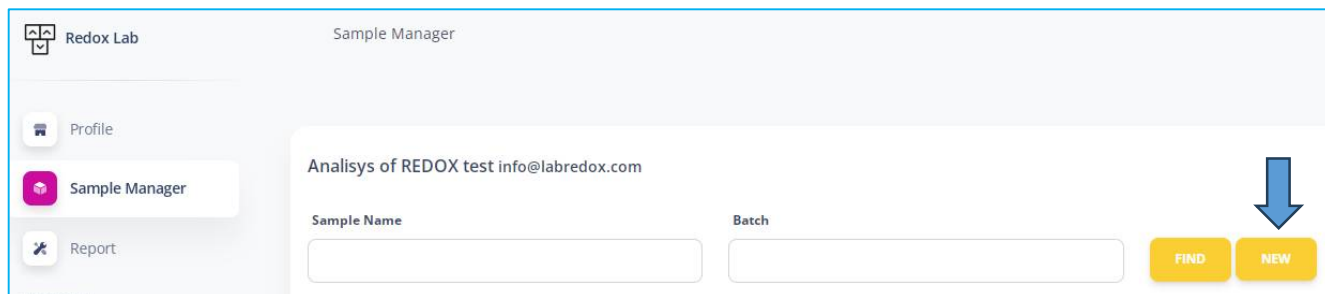
2 info@labredox.com; icp_oea@labredox.com

After entering the information, it’s necessary to save the form by clicking on SAVE.

3.2 Sample Manager

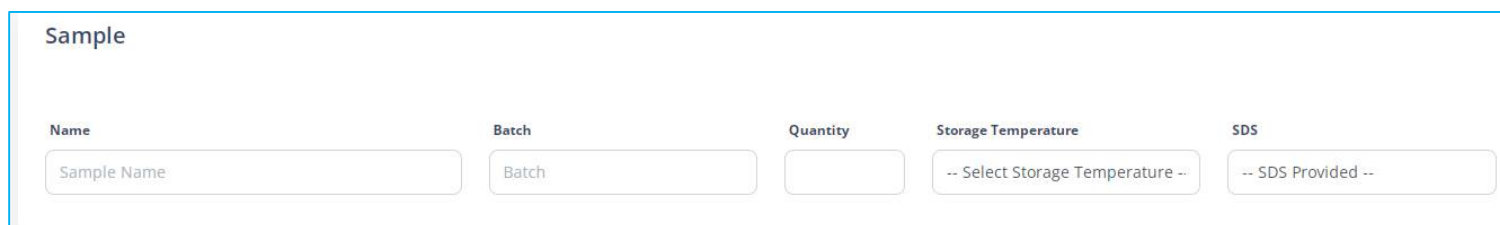
In the tab “Sample Manager” it is possible to insert different **samples**, with their **batches**, and the **analyses** to be performed by Redox.

Clicking on the "New" button the form for inserting a new sample is open.



There are 5 fields, ALL mandatory.

- **Sample name**
- **Batch**
- **Amount of sample sent**
- **Temperature of storage: storage conditions at REDOX**
- **Presence of the Safety Data Sheet:** if the SDS has already been sent to REDOX, no further sending is necessary.



Notes:

- Sample name: in the case of a validated method, in order to facilitate the recognition of the sample by REDOX, it is necessary to enter the name present in the validation report and not internal customer acronyms or code.
- Batch: in case of absence of an identified batch, to continue, it is necessary to fill in the field anyway, inserting for example the "/" symbol.
- Quantity: must be sufficient both for carrying out the analysis and, in case, for a possible OOS investigation
- The “Storage Temperature” and “SDS” fields are drop-down lists in which it is necessary to choose respectively one of the three sample storage conditions (Ambient Temperature; 2-8°C; <15°C) and, if it has been provided the safety data sheet, *Yes* or *No*.

Once all the entries have been filled in, the "**Save**" button appears, which allows to continue with the insertion of the analyses.

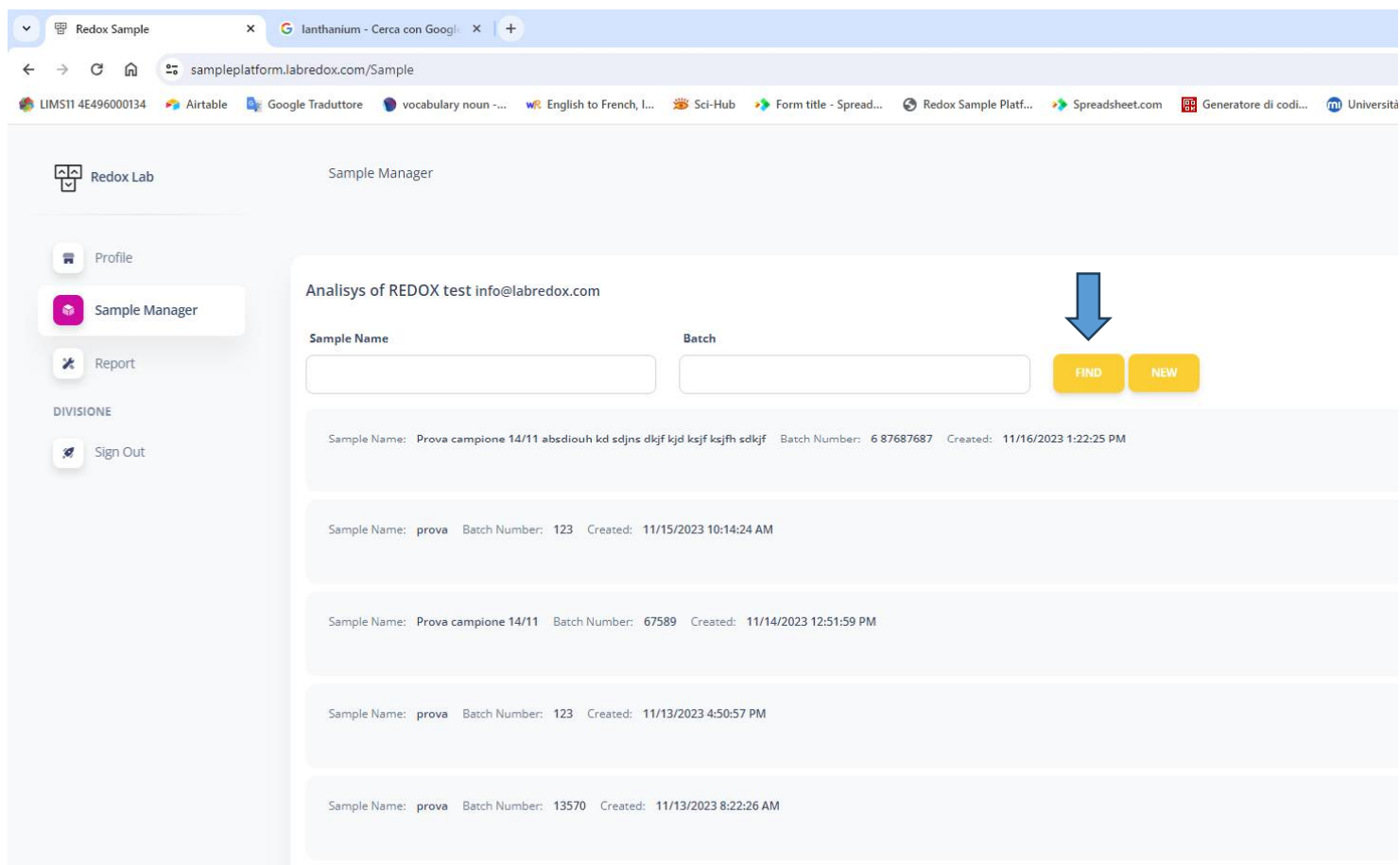
Sample

Name: Batch: Quantity: Storage Temperature: SDS:



In the main window of “Sample Manager” the history of the samples inserted in the past is present.

The “Find” button, allows to search for “Sample Name” and/or “Batch”; the same search is also performed on portions of the string (internal or extreme; see example).



The screenshot shows the 'Sample Manager' interface. On the left is a sidebar with navigation options: Profile, Sample Manager (selected), Report, and Sign Out. The main area is titled 'Sample Manager' and contains a search section with 'Sample Name' and 'Batch' input fields, and 'FIND' and 'NEW' buttons. A blue arrow points to the 'FIND' button. Below the search fields is a list of sample records:

Sample Name	Batch Number	Created
Prova campione 14/11 absdiouh kd sdjns dljfd kjfd ksdf ksdfh sldkf	6 87687687	11/16/2023 1:22:25 PM
prova	123	11/15/2023 10:14:24 AM
Prova campione 14/11	67589	11/14/2023 12:51:59 PM
prova	123	11/13/2023 4:50:57 PM
prova	13570	11/13/2023 8:22:26 AM

Detail of the search.

Redox Sample

sampleplatform.labredox.com/Sample

Redox Lab Sample Manager

Profile

Sample Manager

Report

DIVISIONE

Sign Out

Analysys of REDOX test info@labredox.com

Sample Name Batch

FIND NEW

Sample Name: Prova campione 14/11 absdiouh kd sdjns dlkjf kjd ksif ksifh sdkjf Batch Number: 6 87687687 Created: 11/16/2023 1:22:25 PM

NEW REPORT

3.3 Choice of analytical field and analysis

The first step is the choice between GMP and NON-GMP field.

This phase is very important in order to correctly categorize samples according to their analytical scope. This sample classification must comply with the GMP regulations.

Below is an outline of the purposes:

GMP

(Group 1) – Data for manufacture of pharmaceuticals

- GMP Release (API or Drug Product)
- GMP Release (Starting Material/Intermediate/Excipient/Reagent/Solvent) present in Dossier
- Analytical Certification (Quantitative) of reference/working standard/impurity

(Group 2) – Data for regulatory filing

- Limit test of Impurities (ICH Q2)
- Cleaning
- Stability
- Extractables/Leachables
- Stress testing
- Analysis for Dossier submission (eg.: DMF, ASMF, CEP)

(Group 3) - Other

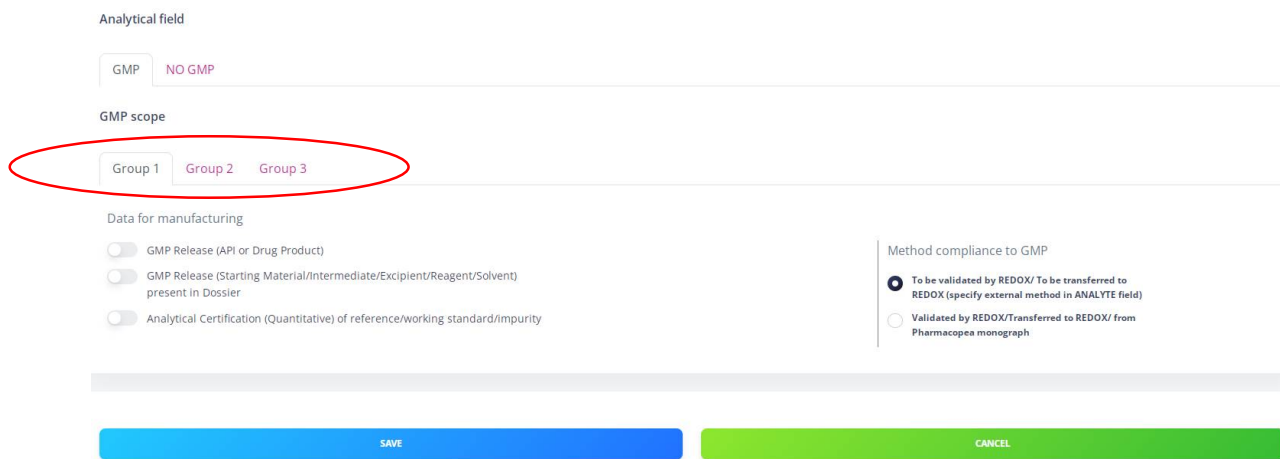
- Other GMP purposes

NON-GMP

- Structural qualitative characterization of API/standard/impurity (NON-GMP)
- GLP Study
- Analytical investigation (NON-GMP)
- Method development (NON-GMP)
- For information only (NON-GMP)
- Other (NON-GMP)
- NOT Pharma

3.3.1 GMP

By selecting the GMP tab, three further tabs, named “Group 1”, “Group 2” and “Group 3” are shown.



Analytical field

GMP NO GMP

GMP scope

Group 1 Group 2 Group 3

Data for manufacturing

- GMP Release (API or Drug Product)
- GMP Release (Starting Material/Intermediate/Excipient/Reagent/Solvent) present in Dossier
- Analytical Certification (Quantitative) of reference/working standard/impurity

Method compliance to GMP

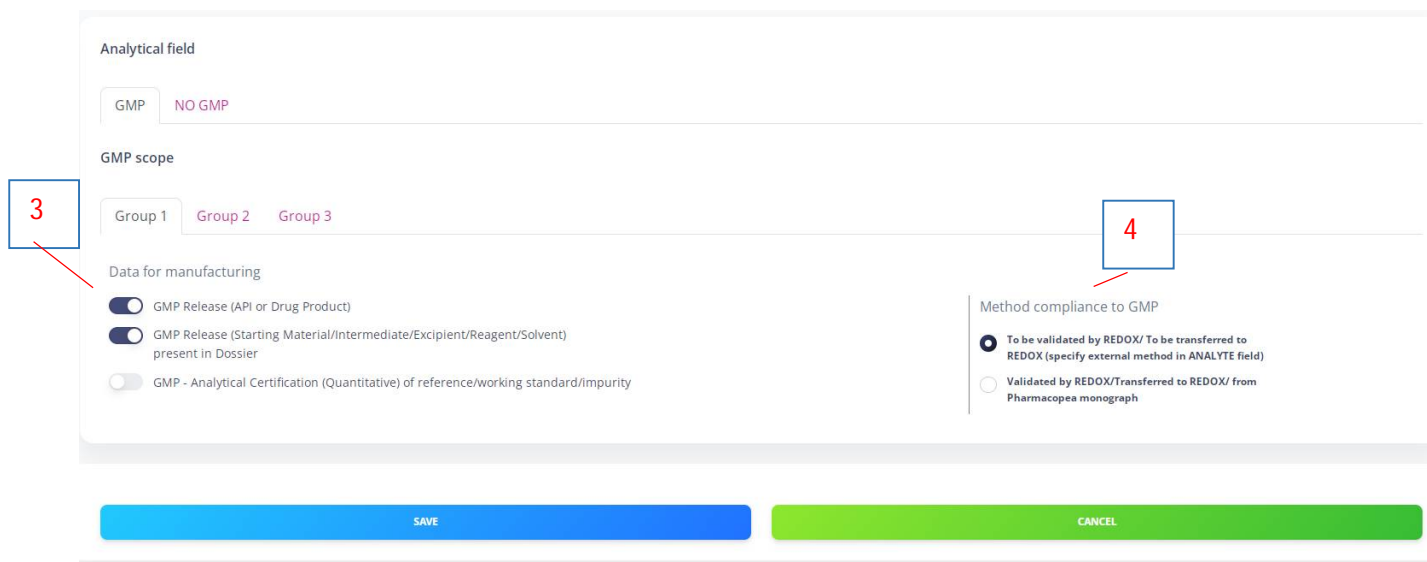
- To be validated by REDOX/ To be transferred to REDOX (specify external method in ANALYTE field)
- Validated by REDOX/Transferred to REDOX/ from Pharmacopea monograph

SAVE CANCEL

Each one of these groups contains different purposes related to the analyses to be performed (see above).

It's necessary to select one or more items (or secondary options) within a SINGLE group (3).

Indeed, it is NOT possible to select items from different groups: therefore, in the case of purposes belonging to different groups, a final choice must be made between them.



Analytical field

GMP NO GMP

GMP scope

Group 1 Group 2 Group 3

Data for manufacturing

- GMP Release (API or Drug Product)
- GMP Release (Starting Material/Intermediate/Excipient/Reagent/Solvent) present in Dossier
- GMP - Analytical Certification (Quantitative) of reference/working standard/impurity

Method compliance to GMP

- To be validated by REDOX/ To be transferred to REDOX (specify external method in ANALYTE field)
- Validated by REDOX/Transferred to REDOX/ from Pharmacopea monograph

SAVE CANCEL

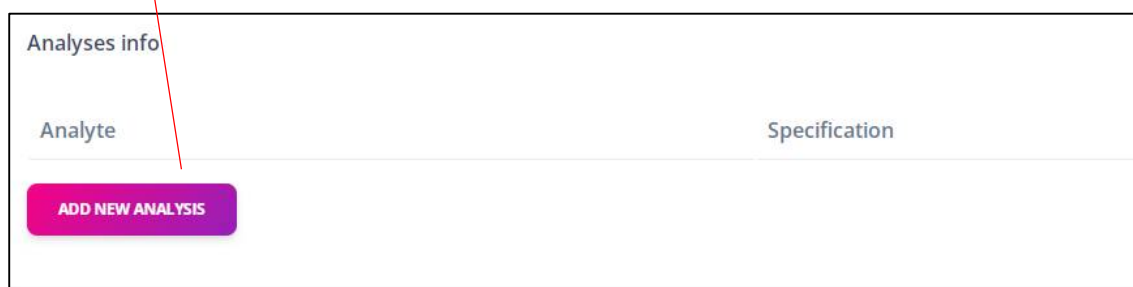
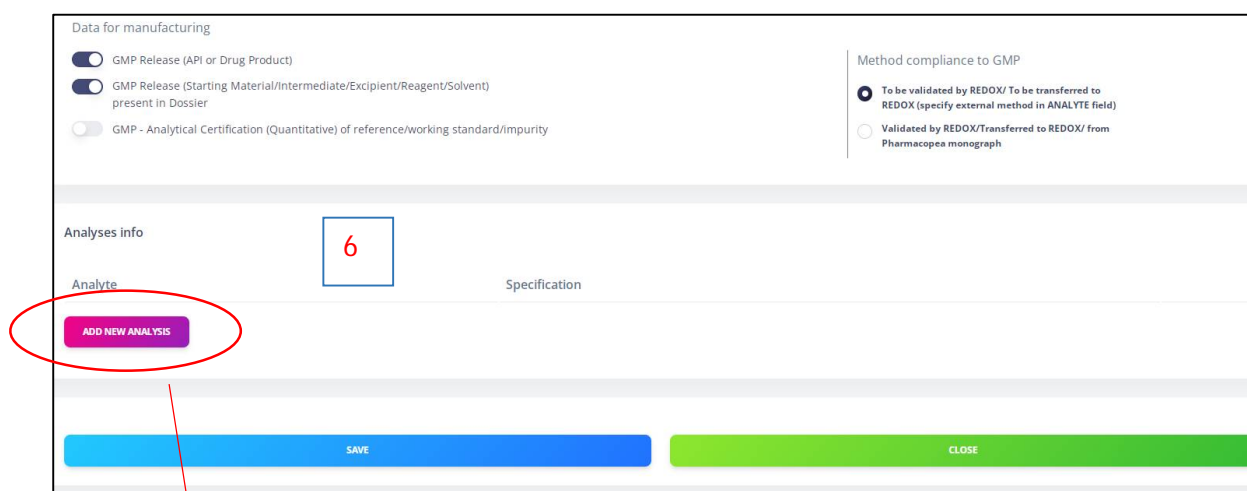
On the right side (4) there is a choice related to the method to be used (see below):

Since GMP field has been selected, there are two available alternatives:

- **Case 1: “To be validated by REDOX/ To be transferred to REDOX (specify external method in ANALYTE field)”**: for methods to be validated by REDOX *or* transferred to REDOX; in the latter case, in the *Analyte field*, it is necessary to indicate the method reference to be transferred (see below).
- **Case 2: “Validated by REDOX/Transferred to REDOX/ from Pharmacopoeia monograph”**: for methods already validated by REDOX *or* already transferred to REDOX *or* provided from Pharmacopoeia MONOGRAPHS

- **Case 1:**

By selecting “*To be validated by REDOX...*”, and saving, the tab “Analyses info” appears (6) below the just filled one. The button “**Add new analysis**” therefore appears.



By clicking “Add new analysis” it is possible to add:

- *ANALYTE*
- *SPECIFICATION*

In the case of a method “to be validated” there is not an official method, hence just type **the analyte** and the **specification** (the economic offer will then redirect to the dedicated sector).

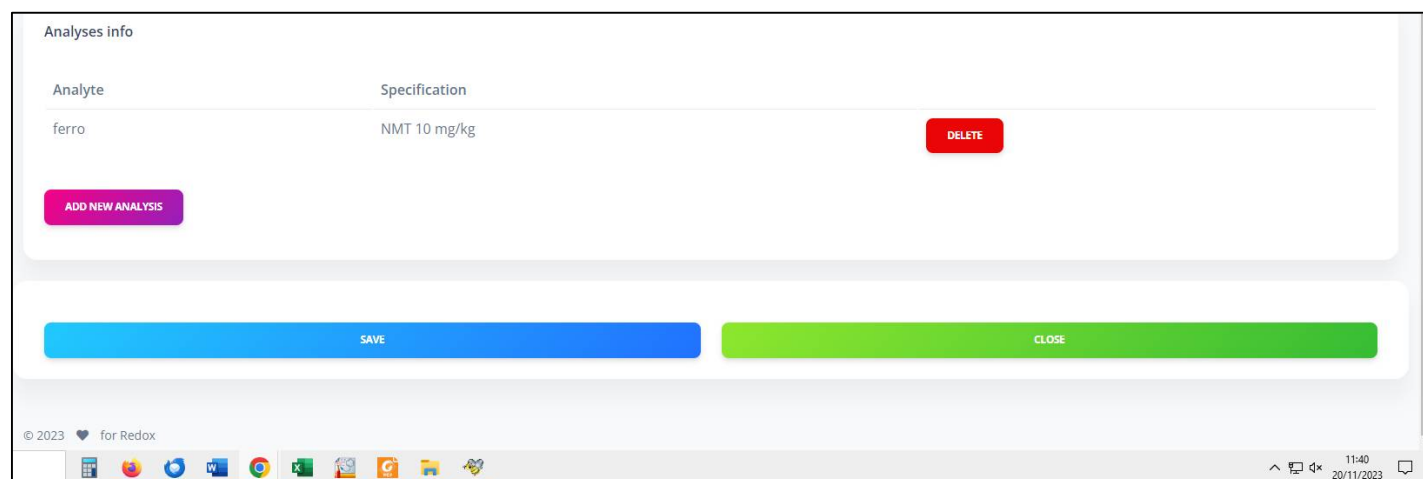


The screenshot shows a modal window titled "Add New Analita" with a close button (X) in the top right corner. It contains two input fields: "Analita" and "Specifiche". Both fields are currently empty. At the bottom right, there are two buttons: a pink "CREATE" button and a grey "CLOSE" button.



The screenshot shows the same "Add New Analita" modal window. The "Analita" field now contains the text "Ferro" and the "Specifiche" field contains "NMT 10 mg/kg". The "Specifiche" field is highlighted with a pink border. The "CREATE" and "CLOSE" buttons are still visible at the bottom right.

By clicking “Create” the analysis is recorded and the “Analyses info” screen (6) appears again and it’s possible to insert a new analyte, in any case remaining in the same GMP field/group and analytical method.

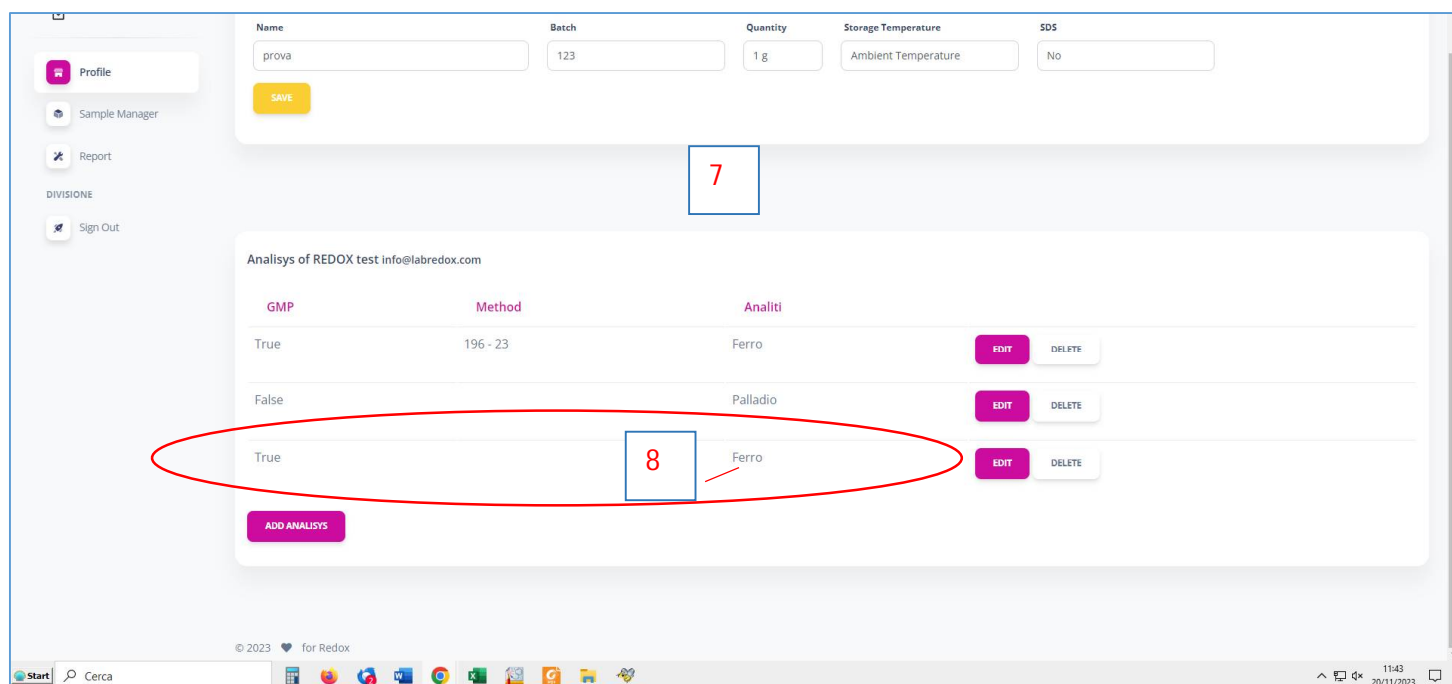


The screenshot shows the "Analyses info" screen. It features a table with two columns: "Analyte" and "Specification". The table contains one row with the values "ferro" and "NMT 10 mg/kg". To the right of this row is a red "DELETE" button. Below the table is a pink "ADD NEW ANALYSIS" button. At the bottom of the screen, there are two large buttons: a blue "SAVE" button and a green "CLOSE" button. The footer of the screen shows "© 2023 for Redox" and a Windows taskbar with the date and time "11:40 20/11/2023".

- For further analytes, click again on “Add new analysis”; repeat the operation for all the analytes.
- In the case of a method “to be transferred to REDOX”, in the Analyte field it’s also necessary to type the reference document of the method to be transferred.
- **All the analysis inserted by this "Analyses info" form will have the same GMP field, group and reference method.**

To insert further analysis, but in DIFFERENT analytical area (GMP/NON-GMP, group, different methods), it's necessary to click "Close" and positioning in the initial screen of the sample (7); click on “Add analysis” and repeat the procedure (see 3.3 – “INSERTING ANALYTICAL FIELD”).

All the entered analysis are indicated in the list of the initial sample screen (8).



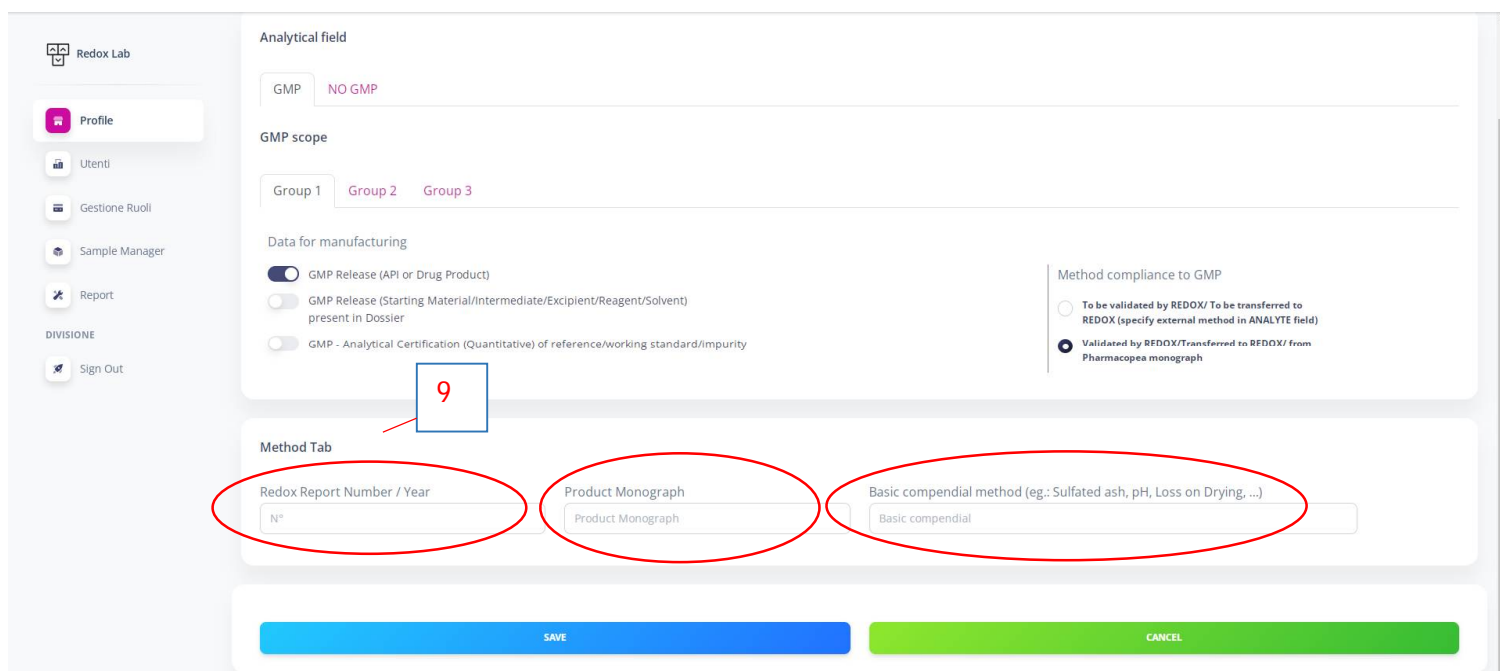
Note: It's always possible to delete (DELETE) or modify (EDIT) the records.

- **Case 2:**

By selecting “*Validated by REDOX...*”, and saving, the “**Method Tab**” (9) immediately appears: it’s mandatory to fill one of the 3 alternatives, mutually exclusive:

- “Redox Report Number/year”: in which it’s necessary to indicate the number of Report to be used for the analysis (e.g. 196/23).
- “Product Monograph”: in which it’s necessary to indicate the **monography** to be used for the analysis (e.g. EP SiO2 monography - 01/2017:0434) (*)
- “Basic compendial method” in which it’s necessary to indicate the analytical method that, for its simplicity and non-specificity, doesn’t need to be validated (e.g. sulfated ash, pH, loss on drying, ...). In the Pharmacopoeia it is identified as "Basic Compendial Method".

(*) **Attention: DO NOT indicate GENERAL methods such as USP233, ICHQ3D, Ph.Eur, because, as to be GMP, they require validation on the specified matrix.**



The screenshot shows the 'Analytical field' configuration page. The 'GMP' section has 'NO GMP' selected. The 'GMP scope' section has 'Group 2' selected. The 'Data for manufacturing' section has three radio buttons, with 'GMP Release (API or Drug Product)' selected. The 'Method compliance to GMP' section has two radio buttons, with 'Validated by REDOX/Transferred to REDOX/ from Pharmacopea monograph' selected. The 'Method Tab' section has three input fields: 'Redox Report Number / Year' (with 'N°' entered), 'Product Monograph' (with 'Product Monograph' entered), and 'Basic compendial method (eg.: Sulfated ash, pH, Loss on Drying, ...)' (with 'Basic compendial' entered). A red box with the number '9' points to the 'Method Tab' header. The 'SAVE' button is blue and the 'CANCEL' button is green.

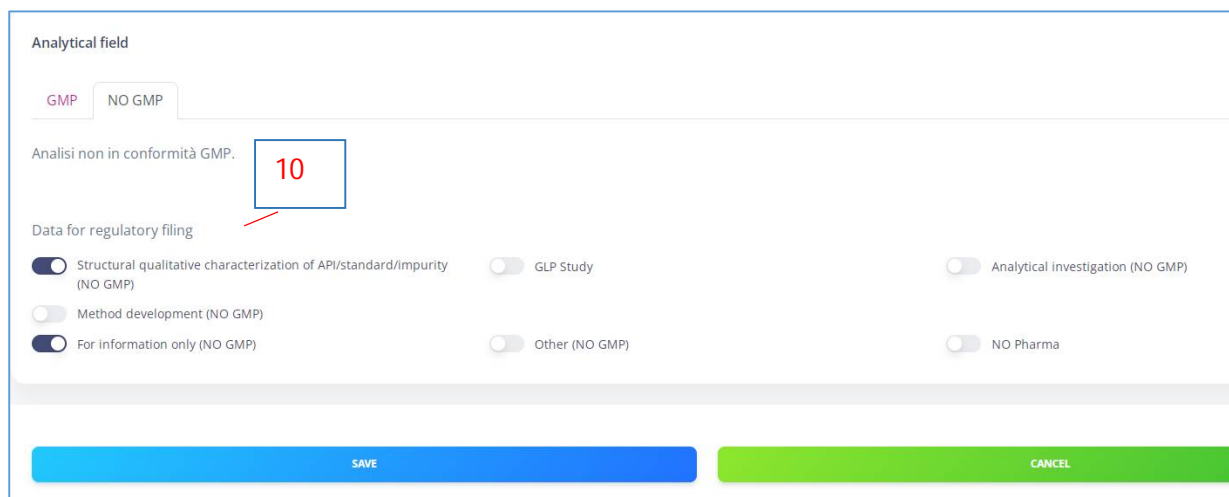
After filling in one of the method fields, the other two are disabled.

It’s now possible to save in order to proceed inserting the analysis: as in Case 1, the “Add New Analysis” tab appears.

Note: the specifications of the individual analyte must obviously be those of the validated method or the Pharmacopoeia method: divergences from these references require an evaluation of the feasibility of the method.

3.3.2 NON-GMP

By selecting the NO GMP tab, different purposes of the analysis to be performed are displayed. It's necessary to select one or more items (10).



Analytical field

GMP NO GMP

Analisi non in conformità GMP. **10**

Data for regulatory filing

- Structural qualitative characterization of API/standard/impurity (NO GMP)
- Method development (NO GMP)
- For information only (NO GMP)
- GLP Study
- Other (NO GMP)
- Analytical investigation (NO GMP)
- NO Pharma

SAVE CANCEL

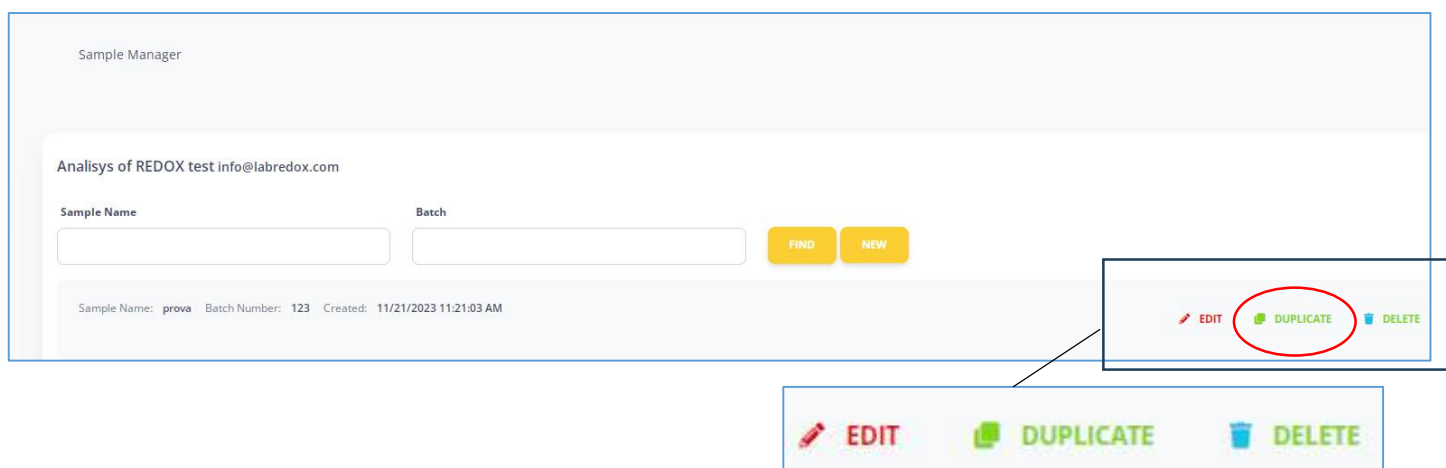
It's now possible to save to proceed and add the analysis to be performed on the sample.

Note: GLP analysis also must be inserted in this group, as they are not GMP.

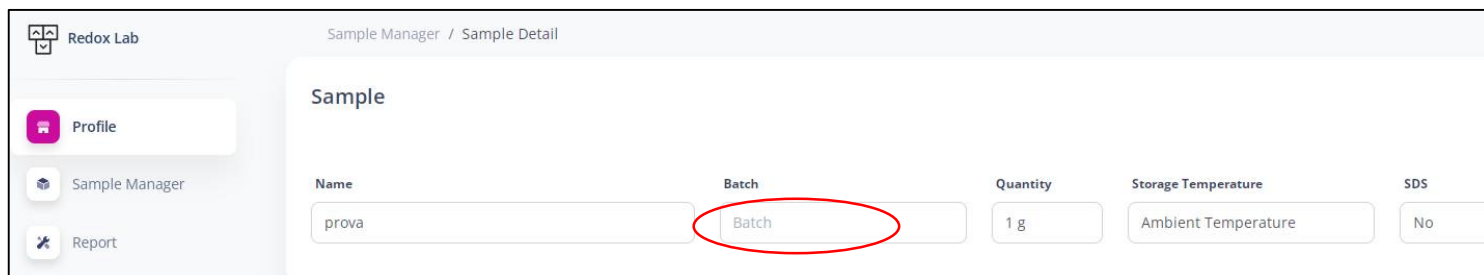
3.4 Duplicate Sample

Also, from "Sample Manager" it's possible to clone an already inserted sample, maintaining all the information (including analysis) and changing ONLY the batch.

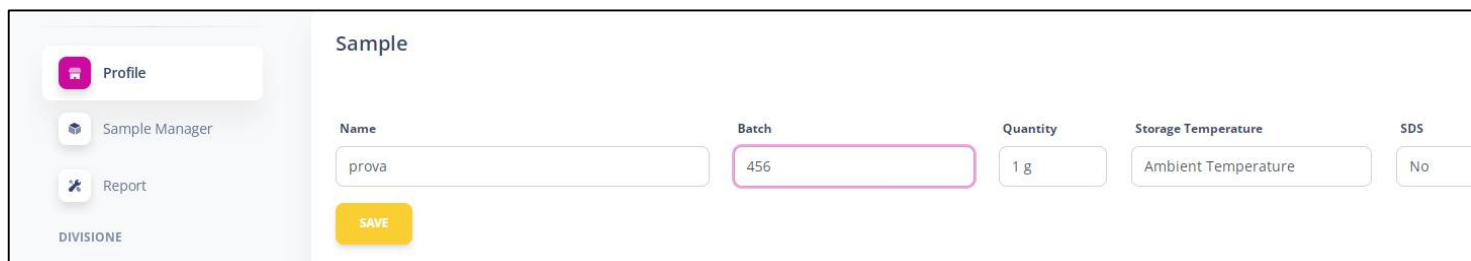
This function is very useful if it is needed to send (simultaneously or at different times) several batches of the same sample with the same analyses.



Simply clicking on the "Duplicate" button related to the sample to be cloned, the pre-populated form related to the data of the new sample will open: ONLY the Batch field has to be filled with the new value.



The "Save" button will appear only after entering the new Batch.



By clicking "Save", the new sample is saved in the database with all the information of the sample from which it was cloned: only the batch is different.

The screenshot displays the 'Sample Manager / Sample Detail' page in the Redox Lab system. On the left is a navigation sidebar with options: Profile, Sample Manager, Report, and Sign Out. The main content area is titled 'Sample' and contains a form with the following fields: Name (prova), Batch (456), Quantity (1 g), Storage Temperature (Ambient Temperature), and SDS (No). A yellow 'SAVE' button is located below the form. Below the form is a section titled 'Analysis of REDOX test info@labredox.com' containing a table with columns for GMP, Method, and Analiti. The table has two rows of data, each with 'EDIT' and 'DELETE' buttons. An 'ADD ANALYSIS' button is located at the bottom of the table.

GMP	Method	Analiti		
True	196 - 23	Ferro	EDIT	DELETE
False		Palladio	EDIT	DELETE

It is always possible to modify the information related to a sample with EDIT, or permanently delete it with DELETE.

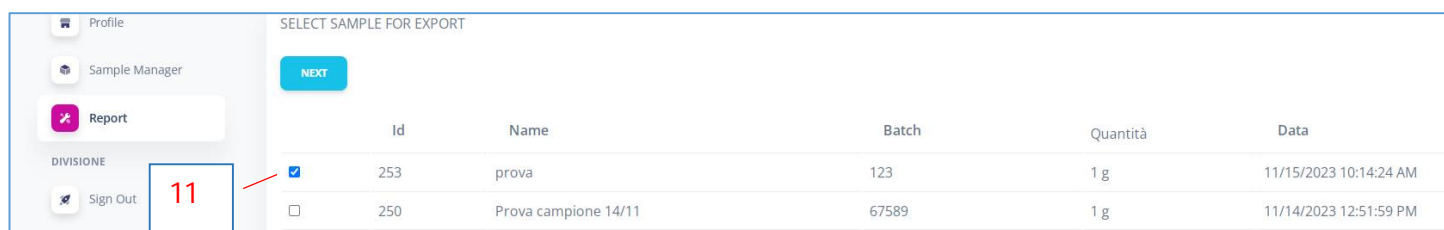
4. PRINT-OUT on paper of the REQUEST LETTER

Once the insertion of all the samples with respective analyses, related to the same shipment, has been completed, the request letter is printed **on paper**.

In the “Report” section it’s possible to select one or more samples to generate the form to print.

The selection is made with a flag at the beginning of the line (11).

All the selected samples will be placed in the same form.

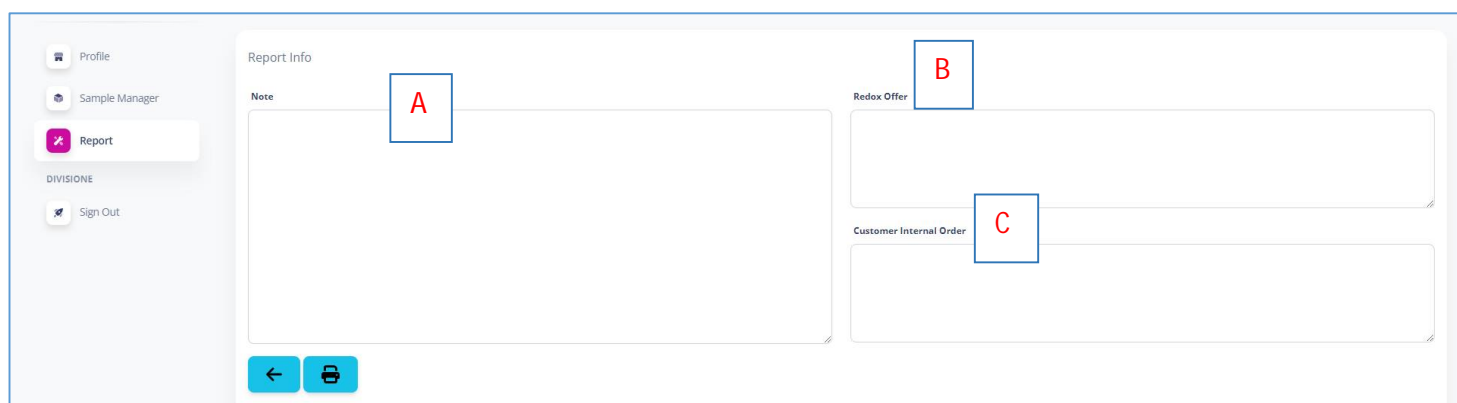


Id	Name	Batch	Quantità	Data	
<input checked="" type="checkbox"/>	253	prova	123	1 g	11/15/2023 10:14:24 AM
<input type="checkbox"/>	250	Prova campione 14/11	67589	1 g	11/14/2023 12:51:59 PM


After selecting the samples, click on the “Next” button.

A prompt opens and allows you to enter:

- A. Notes: indications regarding urgencies, dangers, particular methods of execution
- B. REDOX offer number
- C. Customer order number



These fields are common to all selected samples; therefore, in the case of multiple offers, it will be necessary to enter all the necessary references.

To continue, click on the button with the printer symbol  (12), while to return to the previous page click the “←” button.

Report Info

Note

Eeguire l'analisi del ferro in doppio.
 Palladio atteso in %.
 Attenzione campione pericoloso.


Redox Offer

111/23
123/23

Redox Internal Order

123456789ABC

←



12

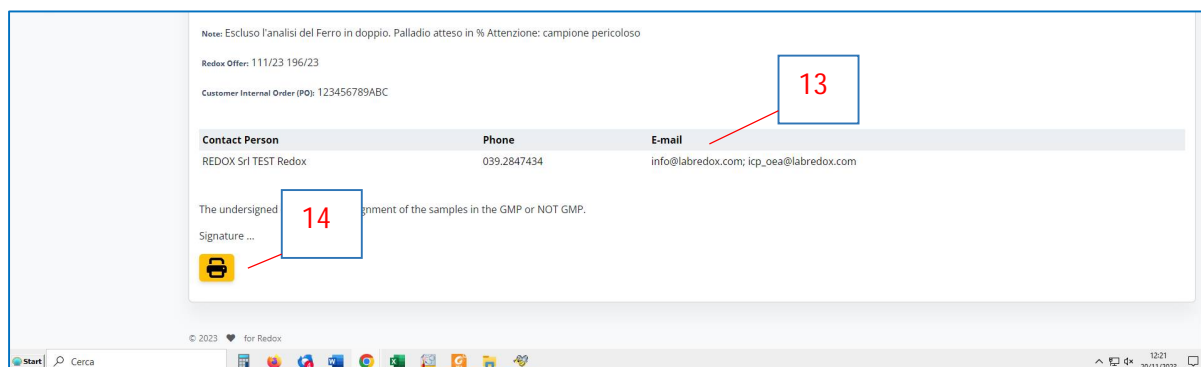
Continuing with the printout, a preview page opens where all the data related to the selected samples are displayed, as well as the information of the company (top) and the applicant (bottom).

Company	Redox
Address	Viale G.B. Stucchi 62/26
Facility(Town)	Monza

Dear REDOX, 20/11/2023
 we hereby provide you the samples reported in the following table, for the execution of the indicated analyses.

Sample Name	Batch	Quantity	Other Info												
prova	123	1 g	<p>Storage: Ambient Temperature</p> <p>SDS: NO</p> <table border="1"> <thead> <tr> <th>Indications</th> <th>Analytical Method</th> <th>Analyte</th> <th>Specification</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> GMP Release (API or Drug Product) </td> <td>Redox Report: 196/23</td> <td>Ferro</td> <td>/</td> </tr> <tr> <td> <p>NO GMP :</p> <ul style="list-style-type: none"> Structural qualitative characterization of API/standard/impurity (NO GMP) For information only (NO GMP) </td> <td>Method</td> <td>Palladio</td> <td>for info</td> </tr> </tbody> </table>	Indications	Analytical Method	Analyte	Specification	<ul style="list-style-type: none"> GMP Release (API or Drug Product) 	Redox Report: 196/23	Ferro	/	<p>NO GMP :</p> <ul style="list-style-type: none"> Structural qualitative characterization of API/standard/impurity (NO GMP) For information only (NO GMP) 	Method	Palladio	for info
Indications	Analytical Method	Analyte	Specification												
<ul style="list-style-type: none"> GMP Release (API or Drug Product) 	Redox Report: 196/23	Ferro	/												
<p>NO GMP :</p> <ul style="list-style-type: none"> Structural qualitative characterization of API/standard/impurity (NO GMP) For information only (NO GMP) 	Method	Palladio	for info												

Note 1: in the case of NOT validated method, the analysis in the CoA will be labelled as "NOT Validated method"
 Note 2: in the case of a General Pharmacopoeia method, if NOT verified on the provided sample matrix, the analysis in the CoA will be labelled as "NOT Validated method"
For analyses with the wording " NOT validated method ", the undersigned is aware that REDOX declines any responsibility in case of use for GMP purposes
 Note 3: If the Material Safety Data Sheet is available, this shall be provided only upon the first shipment of the sample.



Finally, by clicking on the button with the printer (14) the PDF file of the completed form will be generated and downloaded (search in browser download folder), which must be printed-out on paper, signed and attached to the shipment.

Note: the email addresses of the customer to which the analysis certificates will be sent (13), are shown at the bottom of the document and refer to the addresses entered (label 2) in the [profile page](#).

PDF FILE

Company	Redox
Address	Viale G.B. Stucchi 62/26
Facility(Town)	Monza

Dear REDOX, 20/11/2023
we hereby provide you the samples reported in the following table, for the execution of the indicated analyses.

Sample Name	Batch	Quantity	Other Info												
prova	123	1 g	<p>Storage: Ambient Temperature</p> <p>SDS: NO</p> <table border="1"> <thead> <tr> <th>Indications</th> <th>Analytical Method</th> <th>Analyte</th> <th>Specification</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> GMP Release (API or Drug Product) </td> <td>Redox Report: 196/23</td> <td>Ferro</td> <td>/</td> </tr> <tr> <td> <p>NO GMP :</p> <ul style="list-style-type: none"> Structural qualitative characterization of API/standard/impurity (NO GMP) For information only (NO GMP) </td> <td>Method</td> <td>Palladio</td> <td>for info</td> </tr> </tbody> </table>	Indications	Analytical Method	Analyte	Specification	<ul style="list-style-type: none"> GMP Release (API or Drug Product) 	Redox Report: 196/23	Ferro	/	<p>NO GMP :</p> <ul style="list-style-type: none"> Structural qualitative characterization of API/standard/impurity (NO GMP) For information only (NO GMP) 	Method	Palladio	for info
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Note 1: in the case of NOT validated method, the analysis in the CoA will be labelled as "NOT Validated method"
 Note 2: in the case of a General Pharmacopoeia method, if NOT verified on the provided sample matrix, the analysis in the CoA will be labelled as "NOT Validated method"
 For analyses with the wording " NOT validated method ", the undersigned is aware that REDOX declines any responsibility in case of use for GMP purposes
 Note 3: If the Material Safety Data Sheet is available, this shall be provided only upon the first shipment of the sample.

Note: Escluso l'analisi del Ferro in doppio. Palladio atteso in % Attenzione: campione pericoloso
Redox Offer: 111/23 196/23

5 SUMMARY DIAGRAM

Below is a summary of the steps to be performed.

