

NITROSAMINES RISK ELECTRONIC SUBMISSION FORM

INSTRUCTIONS TO APPLICANTS

INFARMED, I.P - DAM

MAH RESPONSABILITIES

TAKING INTO ACCOUNT THEIR KNOWLEDGE OF THE MANUFACTURING PROCESSES AS WELL AS THE POTENTIAL SOURCES OF NITROSAMINE IMPURITIES, MAHs SHOULD WORK WITH MANUFACTURERS OF API AND FINISHED PRODUCTS IN ORDER TO REVIEW THE API AND FINISHED PRODUCT MANUFACTURING PROCESSES WITH RESPECT TO THE ARRANGEMENTS FOR PREVENTING NITROSAMINE FORMATION AS WELL AS CONTAMINATION OR CROSS-CONTAMINATION

STEP 1 RISK EVALUATION: MAHs should perform risk evaluation of their medicinal products containing chemically synthesised API.

STEP 2 CONFIRMATORY TESTING: in the event that a risk of presence of nitrosamines is identified as a result of the risk evaluation, confirmatory testing should be carried out using appropriately validated and sensitive methods in accordance with the prioritisation deriving from the risk evaluation conducted in step 1.

STEP 3 CHANGES TO THE MARKETING AUTHORISATION: MAHs should apply for a variation in a timely manner to introduce any required changes, such as amendment of the manufacturing process or changes to product specifications.

INFARMED, I.P.

An **electronic form** was developed using SMUH-ALTER (national application for submission of Variation), where The MAH directly submits the results of its analysis and nitrosamine risk.

SMUH-ALTER – HOW TO USE THE SUBMISSION FORM?

TO START THE REGISTRATION CLICK ON THE BUTTON “NITROSAMINE RISK ASSESSMENT”

The screenshot shows a web browser window with the URL `http://iis-interno-testes/smuh_alter_gwp/frmPesquisaAlter.aspx`. The page displays user information: **User:** gpon12, **Marketing authorisation holder:** Bayer Portugal, S.A. There are links for [Change Password](#), [Logout](#), [View Documents \(SmPC & PIL\)](#), and [Alerts \(82\)](#). A dropdown menu is set to "Create New Application Marketing Authorization". A pink arrow points to a button labeled "Nitrosamine Risk Assessment".

VARIATION APPLICATIONS

| Name of the medicinal product | Submission Date | Procedure Number | MRP/National variation number |
|-------------------------------|---|---------------------|-------------------------------|
| | From <input type="text"/> To <input type="text"/> (yyyy-mm-dd) | | |
| Procedure Status | Fee Status | Payment Form | Authorisation Type |
| Any | Any | | Marketing Authorization |
| Application Type | Variation Type | Variation | |
| Any | Any | | |

List of Applications to submit

TO SUBMIT THE RISK ANALYSIS, CLICK ON THE
BUTTON “SUBMIT NITROSAMINE ANALYSIS RISK”

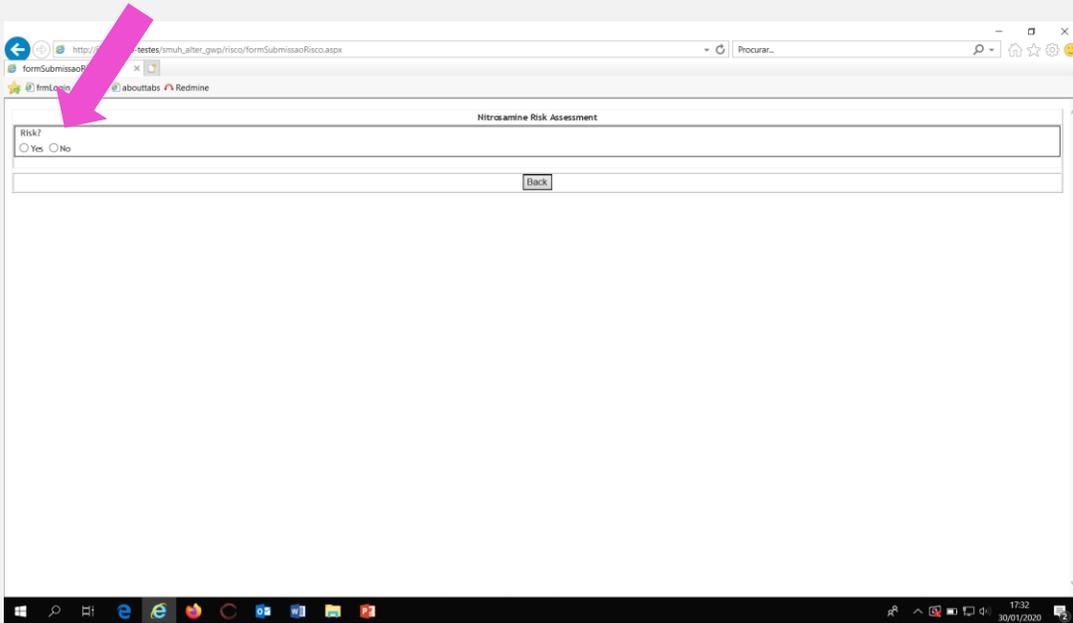
The screenshot shows a web browser window with the URL `http://iis-interno-testes/smuh_alter_gwp/risco/Default.aspx`. The browser's address bar contains the text "Procurar...". The page title is "Default". The browser's tab bar shows "frmLogin", "Login", "abouttabs", and "Redmine".

The main content area displays a form titled "Nitrosamine Risk Assessment". The form is organized into two rows of four columns each. The first row contains the following fields: "Name of the medicinal product", "INN", "Pharmaceutical Form", and "Strength". The second row contains: "Risk" (with a dropdown arrow), "Analysis Scheduled Date" (with a dropdown arrow), "Analysis Result" (with a dropdown arrow), and two buttons: "Clear" and "Search". Below these fields is a prominent blue button labeled "Submit Nitrosamine Analysis Risk". A large pink arrow points from the right side of the screen towards this button.

At the bottom of the form, there is a "Back" button. The browser's taskbar at the bottom shows the Windows logo, search icon, and several application icons (Edge, Firefox, Chrome, Outlook, Word, File Explorer, PowerPoint). The system tray on the right shows the time "17:29" and the date "30/01/2020".

IF YOU WANT TO SUBMIT RISK ANALYSIS TO “NO”

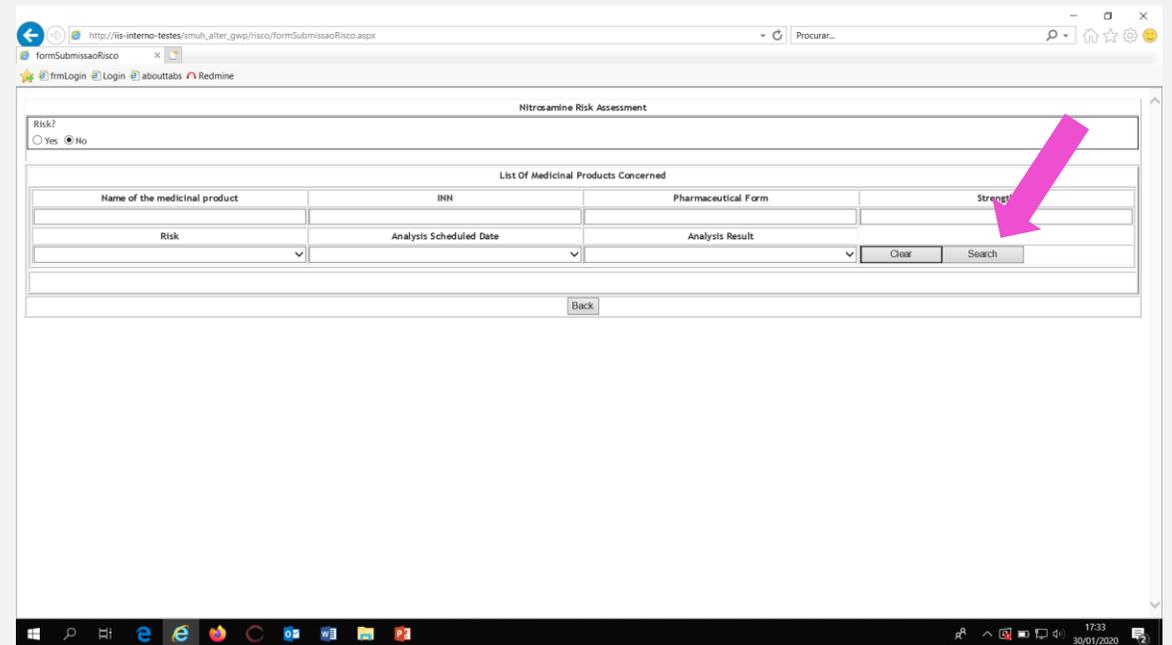
1. Click on “NO”



The screenshot shows a web browser window with the URL `http://ris-internal-testes/smuh_alter_gwp/risco/formSubmissaoRisco.aspx`. The page title is "Nitrosamine Risk Assessment". At the top, there is a "Risk?" section with two radio buttons: "Yes" and "No". The "No" radio button is selected. Below this, there is a "Back" button. The Windows taskbar at the bottom shows the time as 17:32 on 30/01/2020.

2. It is always necessary to include a search criteria

Then click on “Search”



The screenshot shows the same web browser window as the previous one, but now with a "List Of Medicinal Products Concerned" section. This section contains a table with four columns: "Name of the medicinal product", "INN", "Pharmaceutical Form", and "Strength". Below the table, there are two dropdown menus for "Risk" and "Analysis Scheduled Date", and a "Clear" button. The "Search" button is highlighted with a pink arrow. The Windows taskbar at the bottom shows the time as 17:33 on 30/01/2020.

IF YOU WANT TO SUBMIT RISK ANALYSIS TO “NO”

3. After the search, click on the button “Submit” in the line corresponding to the medicinal product for which the risk analysis is to be submitted

Nitrosamine Risk Assessment

Risk?
 Yes No

List Of Medicinal Products Concerned

| Name of the medicinal product | INN | Pharmaceutical Form | Strength |
|-------------------------------|-----|---------------------|----------|
| y | | | |

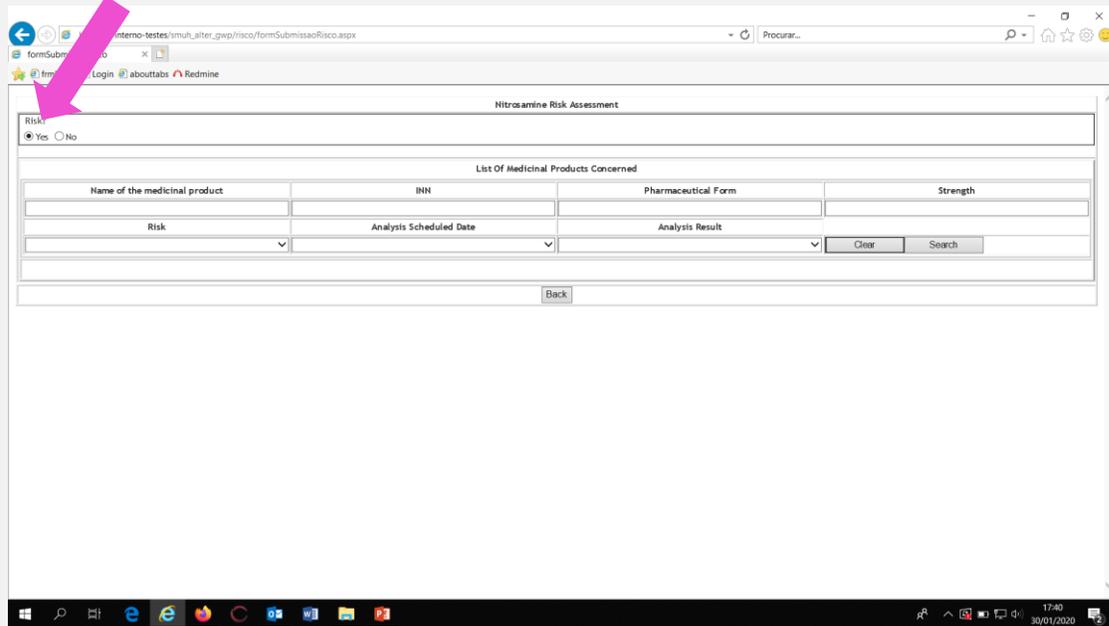
Risk: Analysis Scheduled Date: Analysis Result:

| Name of the medicinal product | INN | Pharmaceutical Form | Strength | Risk | Analysis Scheduled Date | Analysis Result | Submit |
|-------------------------------|---------------------------------|---------------------|--------------------------|------|-------------------------|-----------------|---------------------------------------|
| Baycuten | Dexamethasone + Clotrimazole | Cream | 0.4 mg/g + 10 mg/g | No | | | <input type="button" value="Submit"/> |
| Becozyme Forte | Vitamin B complex + Biotin | Coated tablet | Associação | No | | | <input type="button" value="Submit"/> |
| Gynera | Ethinylestradiol + Gestodene | Coated tablet | 0.03 mg + 0.075 mg | No | | | <input type="button" value="Submit"/> |
| Progyluton | Norgestrel + Estradiol valerate | Coated tablet | (0.5 mg + 2 mg) + (2 mg) | | | | <input type="button" value="Submit"/> |

< Previous Page Next Page >

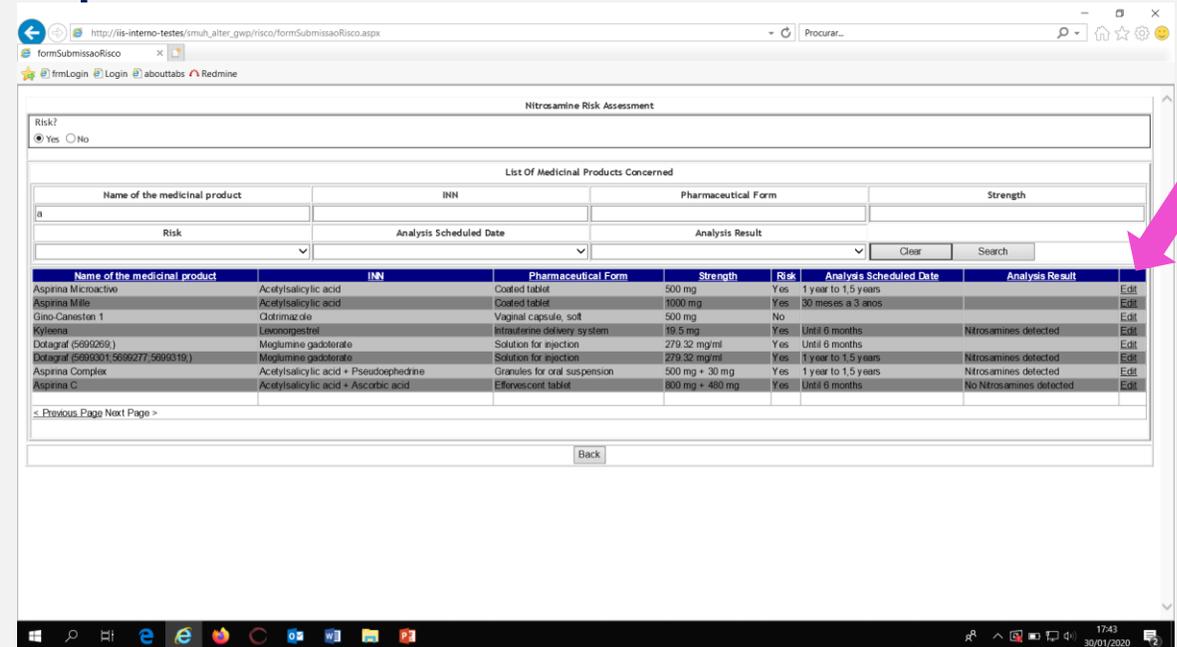
IF YOU WANT TO SUBMIT RISK ANALYSIS TO “YES”

1. Click on “YES”



The screenshot shows the 'Nitrosamine Risk Assessment' form. At the top, there is a 'Risk?' section with two radio buttons: 'Yes' (selected) and 'No'. Below this is a 'List Of Medicinal Products Concerned' section with a table. The table has columns for 'Name of the medicinal product', 'INN', 'Pharmaceutical Form', and 'Strength'. Below the table are dropdown menus for 'Risk', 'Analysis Scheduled Date', and 'Analysis Result', along with 'Clear' and 'Search' buttons. A 'Back' button is at the bottom.

2. Then click the button “Edit” to have access to the medicinal product sheet



The screenshot shows the 'Nitrosamine Risk Assessment' form with the 'Risk?' section set to 'Yes'. Below the 'List Of Medicinal Products Concerned' section, a table of medicinal products is displayed. Each row includes columns for 'Name of the medicinal product', 'INN', 'Pharmaceutical Form', 'Strength', 'Risk', 'Analysis Scheduled Date', and 'Analysis Result'. An 'Edit' button is located at the end of each row. A pink arrow points to one of the 'Edit' buttons.

| Name of the medicinal product | INN | Pharmaceutical Form | Strength | Risk | Analysis Scheduled Date | Analysis Result | Edit |
|------------------------------------|--|------------------------------|-----------------|------|-------------------------|--------------------------|------|
| Aspirina Microactive | Acetylsalicylic acid | Coated tablet | 500 mg | Yes | 1 year to 1.5 years | | Edit |
| Aspirina Mile | Acetylsalicylic acid | Coated tablet | 1000 mg | Yes | 30 meses a 3 años | | Edit |
| Giro-Canesten 1 | Otrimazole | Vaginal capsule, soft | 500 mg | No | | | Edit |
| Kyleena | Levonorgestrel | Intrauterine delivery system | 19.5 mg | Yes | Until 6 months | Nitrosamines detected | Edit |
| Dotagraf (5690269) | Meglumine gadoterate | Solution for injection | 270.32 mg/ml | Yes | Until 6 months | | Edit |
| Dotagraf (5690301;5690277;5690319) | Meglumine gadoterate | Solution for injection | 270.32 mg/ml | Yes | 1 year to 1.5 years | Nitrosamines detected | Edit |
| Aspirina Complex | Acetylsalicylic acid + Pseudoephedrine | Granules for oral suspension | 500 mg + 30 mg | Yes | 1 year to 1.5 years | Nitrosamines detected | Edit |
| Aspirina C | Acetylsalicylic acid + Ascorbic acid | Effervescent tablet | 800 mg + 400 mg | Yes | Until 6 months | No Nitrosamines detected | Edit |

MEDICINAL PRODUCT SHEET- RISK ANALYSIS TO “YES”

In the field “**Analysis Scheduled Date**” the proposed time for carrying out the confirmatory test must be selected. Click on “**Submit**”.

The screenshot shows a web browser window with the URL http://iis-interno-testes/smuh_alter_gwp/risco/Details.aspx?ID=593221. The form contains several fields: a text area for 'Description' with the value 'Não Comercializado', an 'Attached Documents' section with a file named 'rcm.pdf', and a dropdown menu for 'Analysis Scheduled Date' which is currently open, showing options: 'Until 6 months', '6 months to 1 year', '1 year to 1.5 years', '1.5 years to 2 years', '2 years to 2.5 years', and 'Not applicable'. A 'Nitrosamine Concentration' text area is also visible. A pink arrow points to the 'Delete Document' button, and another pink arrow points to the 'Analysis Scheduled Date' dropdown. A blue box labeled 'free writing field' is positioned to the right of the 'Description' field. At the bottom, there are 'Back' and 'Submit' buttons.

In the field “**Analysis Result**” select the final result after the confirmatory test. Click on “**Submit**”.

The screenshot shows the same web browser window as the previous one. The 'Analysis Scheduled Date' dropdown is now closed, and the 'Analysis Result' dropdown is open, showing two options: 'No Nitrosamines detected' and 'Nitrosamines detected'. A pink arrow points to the 'Delete Document' button, and another pink arrow points to the 'Analysis Result' dropdown. A blue box labeled 'free writing field' is positioned to the right of the 'Nitrosamine Concentration' text area. At the bottom, there are 'Back' and 'Submit' buttons.

CHANGE THE RISK ANALYSIS FROM “NO” TO “YES”

1. Click on “**YES**” and insert a search criteria for the medicinal product that is necessary to change the risk. Then click on “**Search**”

Nitrosamine Risk Assessment

Risk: Yes No

| Name of the medicinal product | INN | Pharmaceutical Form | Strength |
|-------------------------------|-----|---------------------|----------|
| | | | |
| | | | |
| | | | |

Analysis Scheduled Date: [Dropdown] Analysis Result: [Dropdown] Clear Search

Back

2. Click on “**Edit**” in the line of the medicinal product to be changed and you will have access to the medicinal product sheet

Nitrosamine Risk Assessment

| Name of the medicinal product | INN | Pharmaceutical Form | Strength | Risk | Analysis Scheduled Date | Analysis Result |
|-------------------------------|----------------------|------------------------|---|------|-------------------------|-----------------------|
| Aspirina Micromax | Acetylsalicylic acid | Coated tablet | 500 mg | Yes | 1 year to 1.5 years | --- |
| Aspirina Micromax | Acetylsalicylic acid | Coated tablet | 100 mg | No | 30 months to 2 years | --- |
| Aspirina Micromax 1 | Aspirin | Vaginal capsules, soft | 500 mg | No | --- | --- |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 50 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 100 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 12800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 25600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 51200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 102400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 204800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 409600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 819200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1638400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3276800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6553600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 13107200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 26214400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 52428800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 104857600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 209715200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 419430400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 838860800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1677721600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3355443200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6710886400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 13421772800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 26843545600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 53687091200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 107374182400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 214748364800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 429496729600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 858993459200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1717986918400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3435973836800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6871947673600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 13743895347200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 27487790694400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 54975581388800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 109951162777600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 219902325555200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 439804651110400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 879609302220800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1759218604441600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3518437208883200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 7036874417766400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 14073748835532800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 28147497671065600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 56294995342131200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 112589990684262400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 225179981368524800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 450359962737049600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 900719925474099200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1801439850948198400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3602879701896396800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 7205759403792793600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 14411518807585587200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 28823037615171174400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 57646075230342348800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 115292150460684697600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 230584300921369395200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 461168601842738790400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 922337203685477580800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1844674407370955161600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3689348814741910323200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 7378697629483820646400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 14757395258967641292800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 29514790517935282585600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 59029581035870565171200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 118059162071741130342400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 236118324143482260684800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 472236648286964521369600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 944473296573929042739200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1888946593147858085478400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3777893186295716170956800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 7555786372591432341913600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 15111572745182864683827200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 30223145490365729367654400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 60446290980731458735308800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 120892581961462917470617600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 24178516392292583494123200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 48357032784585166988246400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 96714065569170333976492800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 193428131138340667952985600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 386856262276681335905971200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 773712524553362671811942400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1547425049106725343623884800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3094850098213450687247769600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6189700196426901374495539200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 12379400392853802748991078400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 24758800785707605497982156800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 49517601571415210995964313600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 99035203142830421991932627200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 198070406285660843983865244800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 396140812571321687967730489600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 792281625142643375935460979200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1584563250285286751870921958400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3169126500570573503741843916800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6338253001141147007483687833600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 12676506002282294014967375667200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 25353012004564588029934751334400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 50706024009129176059869502668800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 101412048018258352119739005337600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 202824096036516704239478010675200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 405648192073033408478956021350400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 811296384146066816957912042700800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1622592768292133633915844045414400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3245185536584267267831688090828800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6490371073168534535663376181657600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1298074214633706907132675363311513600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 2596148429267413814265350726623027200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 5192296858534827628530701533246054400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 10384593717069655257061403066492088800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 207691874341393105141228061329849777600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 415383748682786210282456122659699555200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 830767497365572420564912245319399110400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 1661534994731144841129824490638798220800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 3323069989462289682259648981277596441600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 6646139978924579364519297962555192883200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 13292279957849158729038595925110377665600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 2658455991569831745807719185022075332800 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 5316911983139663491615438370044150665600 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 10633823966279326983230876740088301331200 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 21267647932558653966461754880176660262400 mg/5 ml | Yes | 1 year to 1.5 years | Nitrosamines detected |
| Aspirina Micromax 1 | Aspirin | Oral suspension | 4253529586511730793292350976035332044800 mg/5 ml | Yes | 1 year to 1.5 | |

RISK ANALYSIS “NO” BECAUSE THE MEDICINAL PRODUCT IS NOT MARKETED

Submit the risk “NO”. Then access the medicinal product sheet as if it were a submission “YES” and in the field “DESCRIPTION” write “NOT MARKETED”.

The screenshot shows a web browser window with the URL `http://iis-interno-testes/smuh_alter_gwp/risco/Details.aspx?D=593221`. The page title is "Detalhes". The browser's address bar shows "Procurar...". The page content includes a "Description" field with the text "Não Comercializado", a pink arrow pointing to it, and a table of "Attached Documents (Max: 10 MB)" with one entry: "rcm.pdf" and a "Download" link. Below the table is a "Delete Document" button. There are two dropdown menus: "Analysis Scheduled Date" and "Analysis Result". At the bottom, there is a "Nitrosamine Concentration" field and "Back" and "Submit" buttons. The Windows taskbar is visible at the bottom of the screen.

THANKS

