

SUBMISSÃO DO RISCO DE NITROSAMINAS FORMULÁRIO ELETRÓNICO

INSTRUÇÕES AOS REQUERENTES

INFARMED, I.P - DAM

RESPONSABILIDADES TITULARES AIM

TENDO EM CONSIDERAÇÃO O CONHECIMENTO DOS PROCESSOS DE FABRICO ASSIM COMO AS FONTES POTENCIAIS DE IMPUREZAS DE NITROSAMINAS OS TAIM DEVEM, EM CONJUNTO COM OS FABRICANTES DE API E DOS PRODUTOS ACABADOS, EFETUAR UMA REVISÃO DOS PROCESSOS DE FABRICO DA API E DO PRODUTO ACABADO DE FORMA A EVITAR A FORMAÇÃO DE NITROSAMINAS, BEM COMO A CONTAMINAÇÃO OU CONTAMINAÇÃO CRUZADA.

ETAPA 1 - Avaliação de risco: realização pelos TAIM de uma avaliação de risco dos seus medicamentos que contêm API sintetizada quimicamente.

ETAPA 2 - Teste de confirmação: no caso de ser identificado um risco de presença de nitrosaminas como resultado da avaliação de risco, o teste de confirmação deve ser realizado utilizando métodos validados e sensíveis, de acordo com a priorização decorrente da avaliação de risco realizada na etapa 1.

ETAPA 3 - Alterações na autorização de introdução no mercado: alteração da AIM para introduzir as alterações necessárias, como alteração do processo de fabrico ou alterações nas especificações do produto.

INFARMED, I.P.

Foi desenvolvido um **formulário eletrónico** através do SMUH-ALTER (plataforma nacional para submissão de alterações) de forma a que os TAIM submetam diretamente os resultados das suas avaliações ao risco e testes de confirmação de nitrosaminas.

SMUH-ALTER

COMO UTILIZAR O FORMULÁRIO DE SUBMISSÃO?

PARA INICIAR O REGISTO CLICAR NO BOTÃO “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

PARA A SUBMISSÃO DA ANÁLISE DO RISCO, CLICAR
NO BOTÃO “SUBMIT NITROSAMINE ANALYSIS RISK”

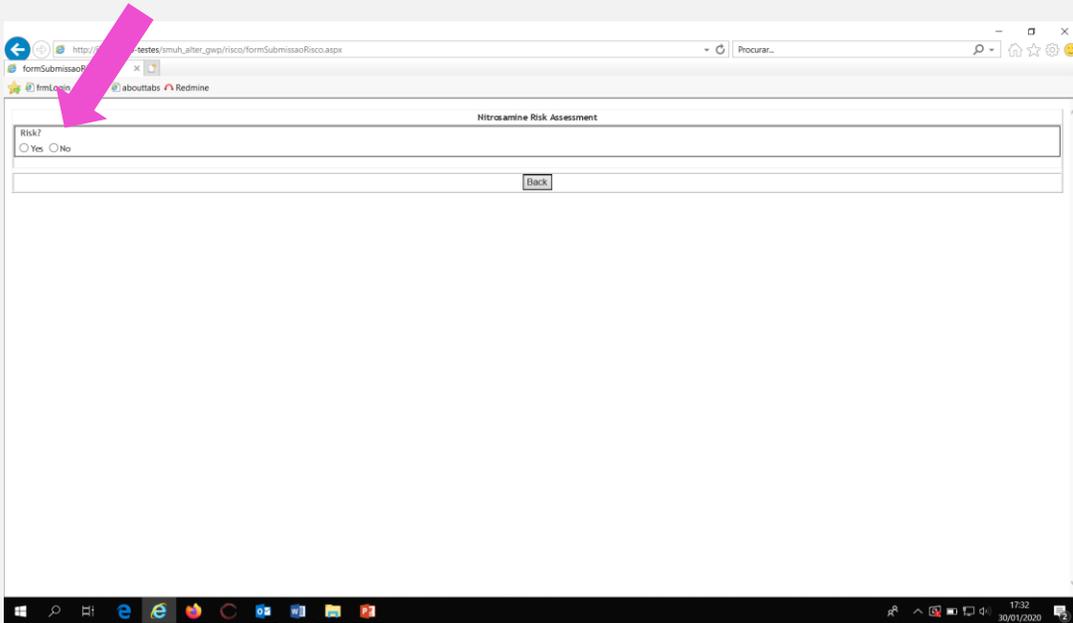
The screenshot shows a web browser window with the URL `http://iis-interno-testes/smuh_alter_gwp/risco/Default.aspx`. The page title is "Nitrosamine Risk Assessment". The form contains the following fields and controls:

Name of the medicinal product	INN	Pharmaceutical Form	Strength
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Risk	Analysis Scheduled Date	Analysis Result	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
			<input type="button" value="Clear"/> <input type="button" value="Search"/>
<input type="button" value="Submit Nitrosamine Analysis Risk"/>			
<input type="button" value="Back"/>			

A pink arrow points to the "Submit Nitrosamine Analysis Risk" button. The Windows taskbar at the bottom shows the date 30/01/2020 and time 17:29.

SE SE PRETENDER SUBMETER ANÁLISE DO RISCO A “NÃO”

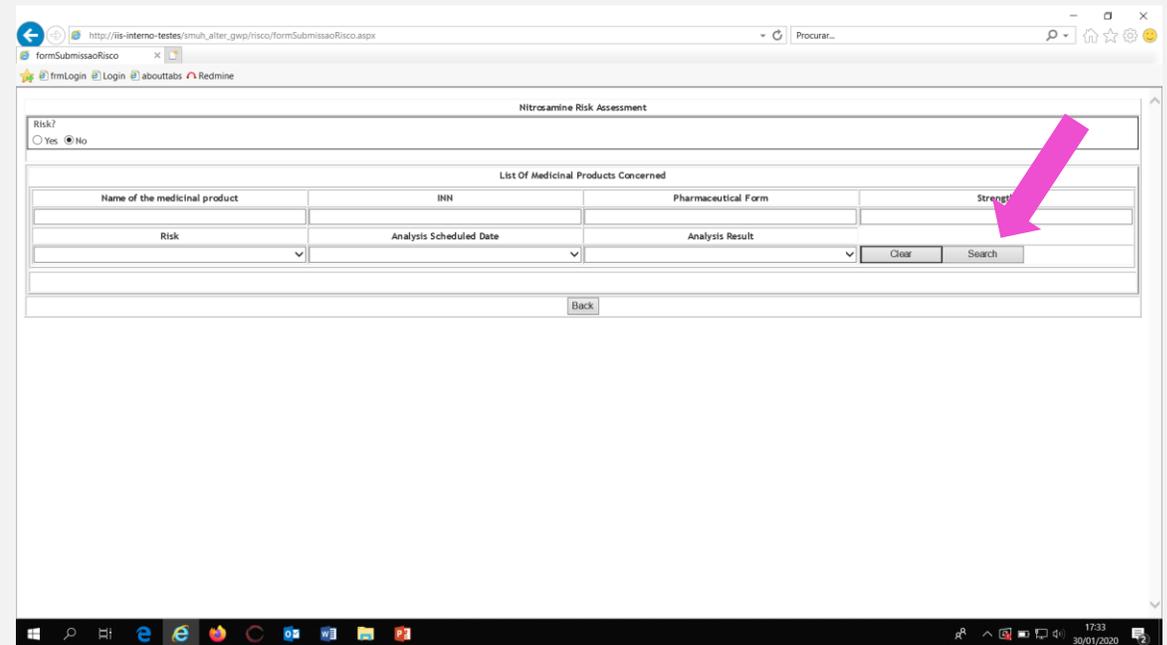
1. Clicar no “NO”



The screenshot shows a web browser window with the URL http://ris-interno-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. A pink arrow points to the "No" radio button.

2. Será sempre necessário incluir um critério de pesquisa

Clicar de seguida em “Search”



The screenshot shows the same web browser window as the previous one, but with the "List Of Medicinal Products Concerned" section expanded. This section contains a table with columns: "Name of the medicinal product", "INN", "Pharmaceutical Form", and "Strength". Below the table, there are dropdown menus for "Risk", "Analysis Scheduled Date", and "Analysis Result". To the right of these dropdowns are "Clear" and "Search" buttons. A pink arrow points to the "Search" button.

SE SE PRETENDER SUBMETER ANÁLISE DO RISCO A “NÃO”

3. Após efetuar a pesquisa, clicar no botão “Submit” na linha correspondente ao medicamento para o qual se pretende submeter a análise do risco

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 >

SE SE PRETENDER SUBMETER ANÁLISE DO RISCO A “SIM”

1. Clicar no “YES”

The screenshot shows the 'Nitrosamine Risk Assessment' form. The 'Risk?' section at the top has radio buttons for 'Yes' (selected) and 'No'. Below this is a section titled 'List Of Medicinal Products Concerned' with a table for data entry. 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. Ao clicar no botão “Edit” terá acesso à ficha do medicamento

The screenshot shows the 'Nitrosamine Risk Assessment' form with the 'Risk?' section set to 'Yes'. Below the 'List Of Medicinal Products Concerned' section is a table listing various medicinal products. The table has columns for 'Name of the medicinal product', 'INN', 'Pharmaceutical Form', 'Strength', 'Risk', 'Analysis Scheduled Date', and 'Analysis Result'. Each row has an 'Edit' button in the rightmost column. A pink arrow points to one of the 'Edit' buttons. Below the table are '< Previous Page' and 'Next Page >' links, and a 'Back' button at the bottom.

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 anos		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

FICHA DO MEDICAMENTO - ANÁLISE DO RISCO A “SIM”

No campo “**Analysis Scheduled Date**” deve ser selecionado o período proposto para a realização do teste confirmatório. Clicar no “**Submit**”

Detalhes

http://iis-interno-testes/smuh_alter_gwp/risco/Details.aspx?ID=593221

Procurar...

Detalhes

frmLogin Login abouttabs Redmine

Description

Não Comercializado

Attached Documents (Max: 10 MB)

File Name	Download
rcm.pdf	Download

Delete Document

Analysis Scheduled Date

- 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
- Not applicable

Nitrosamine Concentration

Back Submit

Campo de escrita livre

No campo “**Analysis Result**” selecionar o resultado final do teste confirmatório. Clicar no “**Submit**”

Detalhes

http://iis-interno-testes/smuh_alter_gwp/risco/Details.aspx?ID=593221

Procurar...

Detalhes

frmLogin Login abouttabs Redmine

Description

Não Comercializado

Attached Documents (Max: 10 MB)

File Name	Download
rcm.pdf	Download

Delete Document

Analysis Scheduled Date

Analysis Result

- No Nitrosamines detected
- Nitrosamines detected

Nitrosamine Concentration

Back Submit

Campo de escrita livre

ALTERAR A ANÁLISE DO RISCO DE “NÃO” PARA “SIM”

1. Clicar no “YES” e como critério de pesquisa colocar informação do medicamento que se pretende alterar o risco. E de seguida clicar “Search”

The screenshot shows the 'Nitrosamine Risk Assessment' form. At the top, there is a 'Risk?' dropdown menu with 'Yes' selected. Below it is a table titled 'List Of Medicinal Products Concerned' with 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', followed by 'Clear' and 'Search' buttons. A pink arrow points to the 'Search' button.

2. Clicar no botão “Edit” na linha do medicamento que se pretende alterar e terá acesso à ficha do medicamento

The screenshot shows the 'Nitrosamine Risk Assessment' form with a populated table. The table has columns: Name of the medicinal product, INN, Pharmaceutical Form, Strength, [X], [X], Analysis Scheduled Date, and Analysis Result. The first row is highlighted, and a pink arrow points to the 'Edit' button in the 'Analysis Result' column.

Name of the medicinal product	INN	Pharmaceutical Form	Strength	[X]	[X]	Analysis Scheduled Date	Analysis Result
Aspirina Microtab	Acetylsalicylic acid	Compressed tablet	100 mg	Yes	1 year to 1.5 years		
Aspirina Microtab 1	Acetylsalicylic acid	Compressed tablet	500 mg	Yes	At least 3 years		
Cardemol	Carbamazepine	Tablet, orally disintegrating	150 mg	No			
Exenatide	Exenatide	Nitrosamine delivery system	10 mg	Yes	Less than 6 months		Nitrosamines detected
Medicine generic	Medicine generic	Tablet for oral use	250 mg	Yes	Less than 6 months		
Medicine generic	Medicine generic	Tablet for oral use	250 mg	Yes	1 year to 1.5 years		Nitrosamines detected
Medicine generic	Acetylsalicylic acid + Phosphoric acid	Granules for oral suspension	500 mg + 50 mg	Yes	1 year to 1.5 years		Nitrosamines detected
Medicine C	Acetylsalicylic acid + Acetylsalicylic acid	Effervescent tablet	800 mg + 800 mg	Yes	Less than 6 months		Nitrosamines detected

3. No campo “Analysis Scheduled Date” deve ser selecionado o período proposto para a realização do teste confirmatório. Clicar no “Submit”

E o risco passará a SIM

The screenshot shows the details page of the 'Nitrosamine Risk Assessment'. It includes a 'Description' field with the text 'Não Comercializado'. Below it is an 'Attached Documents' section with a table showing a file named 'item.pdf'. Below that is the 'Analysis Scheduled Date' dropdown menu, which is set to 'Less than 6 months'. At the bottom, there is a 'Nitrosamine Concentration' field and 'Back' and 'Submit' buttons. A pink arrow points to the 'Submit' button.

ANÁLISE DO RISCO A “NÃO” POR MOTIVO DO MEDICAMENTO NÃO SER COMERCIALIZADO

Carregar o risco como “NO” conforme descrito acima. Em seguida aceder à ficha do medicamento como se fosse uma submissão “YES” e no campo “DESCRIPTION” escrever “NÃO COMERCIALIZADO”.

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" and a pink arrow pointing to it. Below this is an "Attached Documents (Max: 10 MB)" section with a table:

File Name	
rcm.pdf	Download

Below the table is a "Delete Document" button. Further down are two dropdown menus: "Analysis Scheduled Date" and "Analysis Result". At the bottom of the form is a "Nitrosamine Concentration" field and "Back" and "Submit" buttons. The Windows taskbar at the bottom shows the time as 17:51 on 30/01/2020.

OBRIGADA

