

NITROSAMINE SELF-ASSESSMENT



This questionnaire will provide a high-level estimate of your nitrosamine risk exposure.

Does your product contain a small molecule API made by chemical synthesis?

If the answer is no, your product is low risk, so you do not need take this assessment. If the answer is yes, then take the self-assessment below.

Does the API or any of the starting materials used in its synthesis contain an amine group (secondary, tertiary or quaternary)?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Are secondary amines present anywhere in the synthesis, either as a reagent or contaminant?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Do you use solvents that can form amines, e.g. DMF or NMP?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Are nitrites present anywhere in the API synthesis, either as a reagent or contaminant?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Do you routinely test your solvents, both new and recovered, for nitrosamines?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Are there processes in the facility where the API is made that contain secondary amines or nitrites?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Could nitrites be present in your excipients?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Are your products printed with inks containing amines? If yes, are they blister packed using foil with a nitrocellulose lacquer?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>

If your answer to any of these questions is YES or DON'T KNOW then **you have a potential risk of nitrosamine contamination** and need to answer one further question:

Do you routinely test your product for the presence of nitrosamines at the ppb level?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
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If your answer to this question is NO then **you have a potential risk of nitrosamine contamination in your product** and need to implement risk reduction actions.

Remember the conclusions of your risk assessments need to be communicated to the EU Authorities by October 1, 2020.

If you need help in performing your nitrosamine risk assessment or identifying risk reduction actions please contact NSF at pharmamail@nsf.org

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