August 2022

CMDh/411/2019, Rev. 2

**Template for the notification of step 2 confirmatory testing outcome: confirmation of no nitrosamine detected**

*(< FROM MAH ON HEADED PAPER >)*

<Date>

*Name of company,*

*Address*

**RE: Confirmatory testing outcome: confirmation of no nitrosamine detected**

Dear <Name>,

I herewith confirm that,

**☐** having performed the requested confirmatory testing for the product <Name>, <Active Pharmaceutical Ingredient>, <Marketing Authorisation Number>, <EU Procedure Number (for MRP/DCP products only)>, no nitrosamine presence was identified.

I herewith confirm that the testing activities performed were adequately documented and related documentation can be made available upon request.

**☐** for the product <Name>, <Active Pharmaceutical Ingredient>, <Marketing Authorisation Number>, <EU Procedure Number (for MRP/DCP products only) Step 1 outcome is amended to „no risk“ due to new/additional information received from e.g. the API or excipient manufacturer and under consideration of all root causes and the published guidance**.**[[1]](#footnote-1)

Yours sincerely,

<Signature of authorised contact person>

<MAH>

1. In exceptional cases due to the availability of formerly missing data, a correction of step 1 outcome from “risk” to “no risk” is accepted. With ticking the box you confirm that the correction is made due to exceptional cases where data was missing at the March 2020 deadline and is now available. This tickbox may not be used for changes of step 1 outcome from “no risk” to “risk”. In these cases you are required to proceed without delays with Step 2 confirmatory testing and, as applicable, Step 3 submission of required changes to the Marketing Authorisation in accordance with the published guidance. [↑](#footnote-ref-1)