**Template for the notification of step 2 confirmatory testing outcome: confirmation of nitrosamine detected**

*(< FROM MAH ON HEADED PAPER >)*

<Date>

*Name of company,*

*Address*

**RE: Confirmatory testing outcome: confirmation of 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)>, the following nitrosamine(s) was identified: <List the type of nitrosamine(s) identified>.

I also confirm that having performed the required investigations the (preliminary) root cause identified is: <Specify the root cause>.

Details on the amount of the nitrosamines identified are available expressed in ppm in the attached excel spreadsheet.

I herewith enclose the (preliminary) investigation report and I confirm that the testing activities performed were adequately documented and related documentation can be made available upon request.

Yours sincerely,

<Signature of authorised contact person>

<MAH>