QUESTIONNAIRE FOR MUTAGENIC IMPURITIES ASSESSMENT

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In order to perform a toxicological evaluation of the mutagenicity/genotoxicity potential of an organic impurity, its chemical structure should be provided.

Furthermore, when the evaluation is focused on all the mutagenic impurities related to a drug substance/product, information on its route of synthesis (ROS) should be provided, as well as the information obtained from its stability data.

Please note that this information is necessary for performing an accurate and reliable risk assessment. The purpose of this questionnaire is to compile and interpret the results on the actual and potential impurities to evaluate their mutagenicity/genotoxicity potential. In this way, the conclusions extracted in the subsequent risk analysis will be reliable for regulatory purposes.

REGULATORY REQUIREMENTS	
Is the mutagenic/genotoxic evaluation required as part of a registration dossier of a new drug substance or an already marked substance?	YES ☐ NO ☐
Does a deficiency letter of a governmental agency exist in relation to the impurity, and if so, what are the requirements?	YES ☐ NO ☐
IMPURITY DESCRIPTION	
Mutagenicity/genotoxicity assessment for a single impurity: • Impurity description: chemical name, CAS registry number, SMILES notation, molecular weight and molecular formula… (please specify if known)	
Mutagenicity/genotoxicity assessment for the array of impurities related to a drug substance/product (in compliance with ICH M7 guideline) * • Information on the route of synthesis (ROS) of the product (reagents, solvents and catalysts involved) and purification processes (please specify if known) • Impurities already identified in the final drug substance or product (chemical characterization)	
PRODUCT DESCRIPTION	
Administration route of the pharmaceutical product	
Maximum daily dose of the pharmaceutical product	
Average treatment duration (Lifelong treatment, chronic exposure, short-term exposure, single administration)	

** ICH M7 assessment comprises mutagenicity/genotoxicity revision of both actual and potential impurities which could arise from the synthesis or degradation of the drug product.*

Your contact details:

_____
company name for the report

_____
company address for the report

_____
customer name

_____
email phone number

_____
billing address of the company (if different)

_____
comments

Please return to:
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