QUESTIONNAIRE FOR ORGANIC IMPURITIES ASSESSMENT

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In order to perform a toxicological evaluation and risk assessment of the organic impurity under review, its chemical structure should be provided. Furthermore, information on the product administration route, the maximum daily intake and the treatment duration should also be provided by the client.

Please note that this information is necessary for performing an accurate and reliable toxicological evaluation and risk assessment. The purpose of this questionnaire is to compile and interpret the results on both the impurity and the drug product. In this way, the conclusions extracted in the subsequent risk analysis will be reliable for regulatory purposes.

REGULATORY REQUIREMENTS	
Is the toxicological evaluation of the organic impurity required as part of a registration dossier?	YES ☐ NO ☐
Is it necessary to set a specification for the organic impurity in the finished product?	YES ☐ NO ☐
Does the impurity appear as an out of tendency or out of specification result?	YES ☐ NO ☐
Does a deficiency letter of a governmental agency exist in relation to the organic impurity, and if so, what are the requirements?	
IMPURITY DESCRIPTION	
Impurity described in Pharmacopoeia (Ph. Eur, USP)	YES ☐ NO ☐
Impurity description: Chemical name, CAS registry number, SMILES notation, molecular weight and molecular formula… (please specify if known)	
Are there any internal preclinical tests performed? (either with the product containing the impurity or the isolated impurity, please specify if available)	
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)	

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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