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RISK ASSESSMENT OF ELEMENTAL IMPURTIES FOR MANUFACTURING THE DRUG SUBSTANCE (ICH Q3D)

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BACKGROUND

The new ICH Q3D guideline has been recently developed to define and provide a global policy for evaluating and limiting Elemental Impurities in drug products. Thus, a risk assessment and appropriate control of Elemental Impurities according to this guideline have become necessary.

PURPOSE

The purpose of this study is to explain the risk assessment approach for limiting the presence of Elemental Impurities on the drug substance.

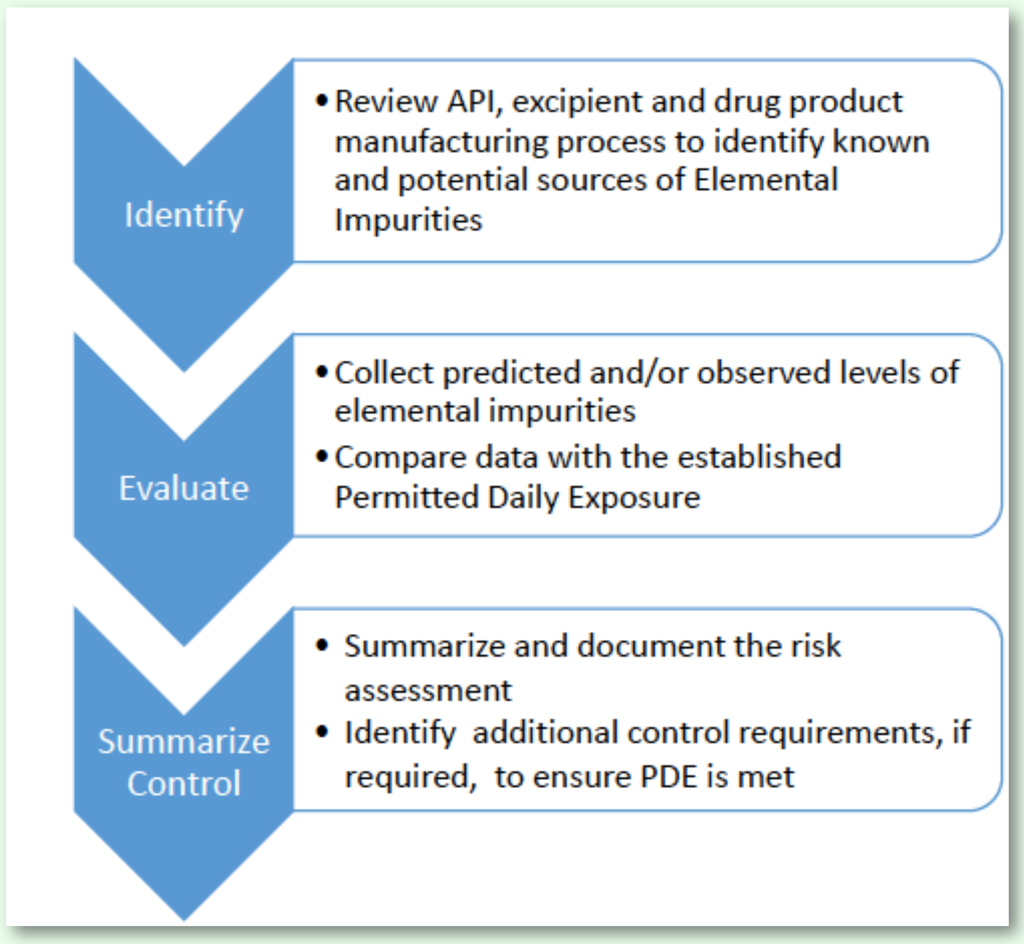
Material and methods

- According to the guidelines ICH Q3D, the identification of Elemental impurities of concern and their potential sources of occurrence is realized.
- The possible levels of Elemental Impurities were determined based on published literature and provided information from suppliers.
- The determined level was then compare with the Permitted Daily Exposure (PDE) defined in ICH Q3D.
- All of these assessment results were summarized into one single assessment sheet for each manufacturing step.

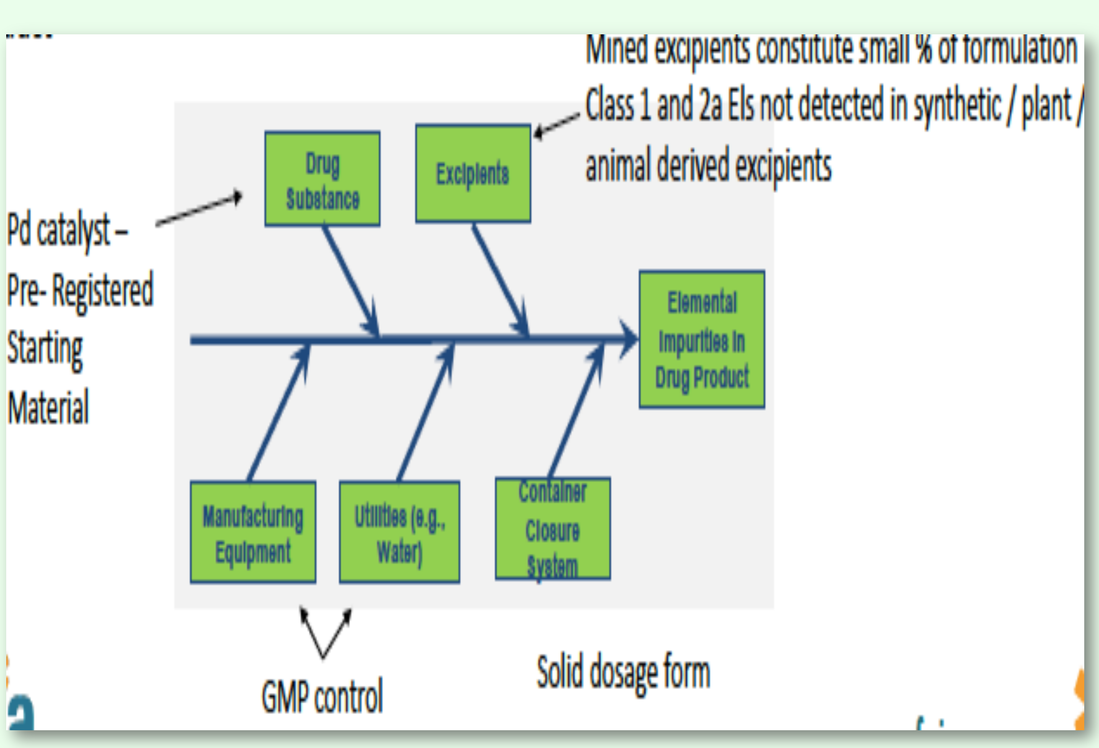
Results

ICH Q3D advocates a 3 step process:

- Identify
- Evaluate
- Summarize Control



- The potential sources of elemental impurities have been identified and several possible sources of class 1 and 2A elemental impurities have been identified.



CONCLUSION

The risk analysis approach provided a complete risk assessment of potential elemental impurities in the drug substance. All potential sources of Elemental Impurities of concern for the manufacturing process of the drug substance were mapped together with the control strategy in the proposed assessment sheet.