First Purchasing and Quality Assurance Supplier Consulting Firm for Drug Manufacturers

Risk analysis : Nitrosamines existence

FORMATION

RISK ANALYSIS

ELECTRONC REPORT

PAPER REPORT

Context :

Following the EMA notification of 19 September 2019 regarding the presence of nitrosamines in drugs, a risk analysis was developed by SH CONSULTING. This analysis is mainly based on the of EMA recommendations : synthesis of the active ingredient, drug utilization, ...

Objective ?

To determine the risk of nitrosamines in products.

Who is involved ?

All manufacturers of drugs for human use including generics and OTC drugs.

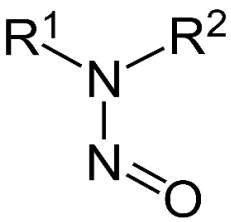
When ?

Within 6 months of the publication of EMA's application before 26 March 2020.

Repositories

- *EMA: Information on nitrosamines for marketing authorisation holders EMA/189634/2019 (19/09/2019)*
- *EMA: Questions and answers on" Information on nitrosamines for marketing authorisation holders" EMA/CHMP/428592/2019 Rev.1 (09/10/2019)*
- *EMA: EMA to provide guidance on avoiding nitrosamines in human medicines*
- *FDA: General advice letter*
- *ICH Q9: Quality Risk Management*
- *ICH M7: Mutagenic impurities*

Possible customizations and adaptations based on requests



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