GMP Webinar Series on Impurities – Highlights and Updates

- European Pharmacopoeia Activities on Elemental Impurities and Nitrosamines, 30 June 2020, 14.00 – 15.30 h CEST
- Impurities coming from Supply Chains, 14. July 2020, 14.00 – 15.30 h CEST
- Mutagenic Impurities with Focus on Nitrosamines – What do Regulatory Authorities Expect? 02 September 2020, 14.00 – 15.30 h CEST

ECA Academy
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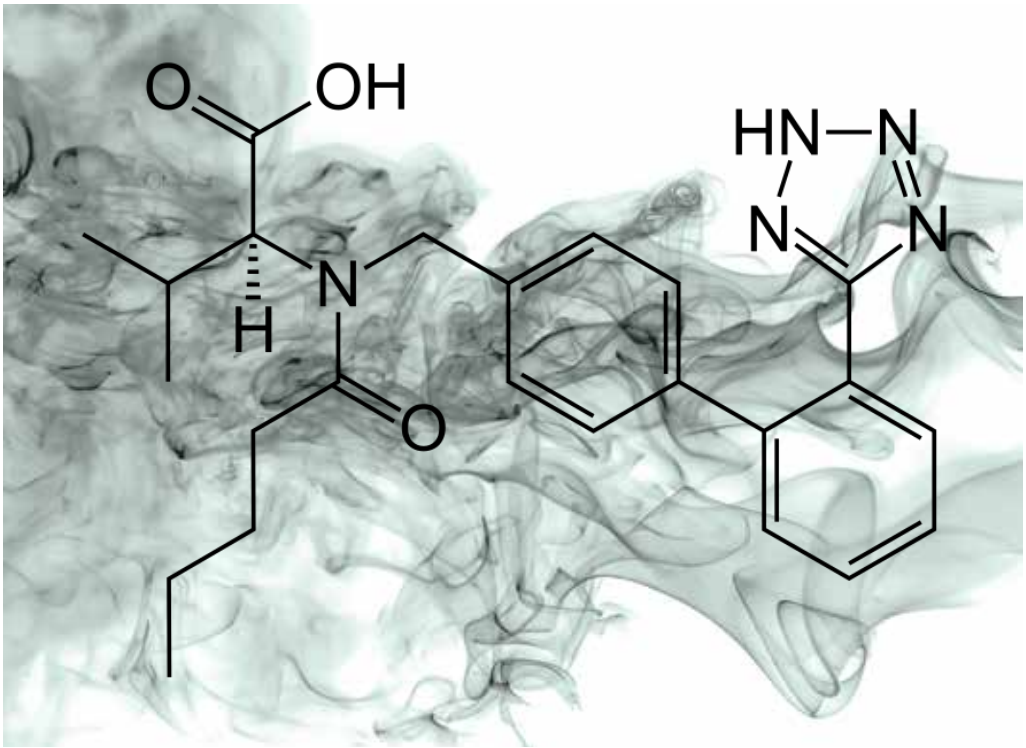
GMP Webinar Series on Impurities – Highlights and Updates

Mutagenic Impurities with Focus on Nitrosamines – What do Regulatory Authorities Expect?

Date:
Wednesday, 02 September 2020, 14.00 – 15.30 h CEST

Speaker:
Dr Corina Nachtsheim, BfArM, Germany



ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

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Background

In June 2018 EU authorities were notified that a Chinese API manufacturer has detected the presence of N-nitrosodimethylamine, NDMA, in batches of Valsartan. Meanwhile different Nitrosamines (NDMA, NDEA and others) were detected in several drug products containing Sartan derivatives as an API. NDMA is a genotoxic and carcinogenic agent in animals and is classified as a Class 2A carcinogen to humans. Therefore Marketing Authorisation Holders are requested to evaluate the risk of the presence of Nitrosamine impurities in human medicinal products containing chemically synthesised APIs and to take immediate steps to avoid nitrosamines in human medicines. As a consequence in case of any contamination with mutagenic impurities Marketing Authorisation Holders have to file a variation application. All regulatory activities with regard to such cases have to be completed within a 3 years period.

Educational Objectives

This webinar will provide an update of the expectations of regulatory authorities with respect to mutagenic impurities with focus on Nitrosamines.

The following topics will be addressed:

- Overview ICH M7 principles
- Nitrosamines – the Valsartan case
- Limits, interim limits and acceptable intakes
- Deadlines for submitting risk assessments
- Variation procedures

A representative of a Regulatory Authority will explain the assessors approach in the assessment of dossiers in particular with respect to the Impurities section.

Target Audience

The webinar addresses all personnel involved in development of drug substances and drug products from scientific staff to laboratory heads involved in R&D. The needs of Laboratory Managers, Supervisors and Analysts in pharmaceutical quality assurance and quality control departments will also be covered. This event will also address regulatory requirements and hence is applicable to people working in the regulatory affairs area.

Speaker

Dr Corina Nachtsheim, BfArM, Germany

Dr Corina Nachtsheim is working as a quality assessor at the German Federal Institute for Drugs and Medical Devices (BfArM) since Jan. 2001. Since Nov. 2007, she is an external expert in the framework of the certification procedure of the EDQM in Strasbourg. She became a member of the chemical Technical Advisory Board (EDQM) in Nov. 2011 which she chaired from Dec. 2013 to Dec. 2019.

Fees (plus VAT)

Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership.
You will find more about the ECA Membership at
https://www.gmp-compliance.org/about-the-academy).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons EUR 211,15
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

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Do you have any questions?

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For questions regarding organisational aspects please contact:
Ms Marion Grimm, phone +49(0)6221 / 84 44 18
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Registration for the GMP Webinar "Mutagenic Impurities with Focus on Nitrosamines – What do Regulatory Authorities Expect?"
on Wednesday, 02 September 2020, 14.00 – 15.30 h CEST
Speaker: Dr Corina Nachtsheim
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:

- ☐ **Single Participation**
- ☐ **Group Participation**
  - ☐ 3-10 Persons
  - ☐ 11-20 Persons
  - ☐ more than 20 Persons

Important: Deadline is 12.00 h on 01 September 2020

Title, First Name, Last Name

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General Terms and Conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.
CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

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German law shall apply. Court of jurisdiction is Heidelberg.