GMP Webinar Series on Impurities – Highlights and Updates

- Mutagenic Impurities with Focus on Nitrosamines – What do Regulatory Authorities Expect? 29 June 2020, 14.00 – 15.30 h CEST
- 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

ECA Academy
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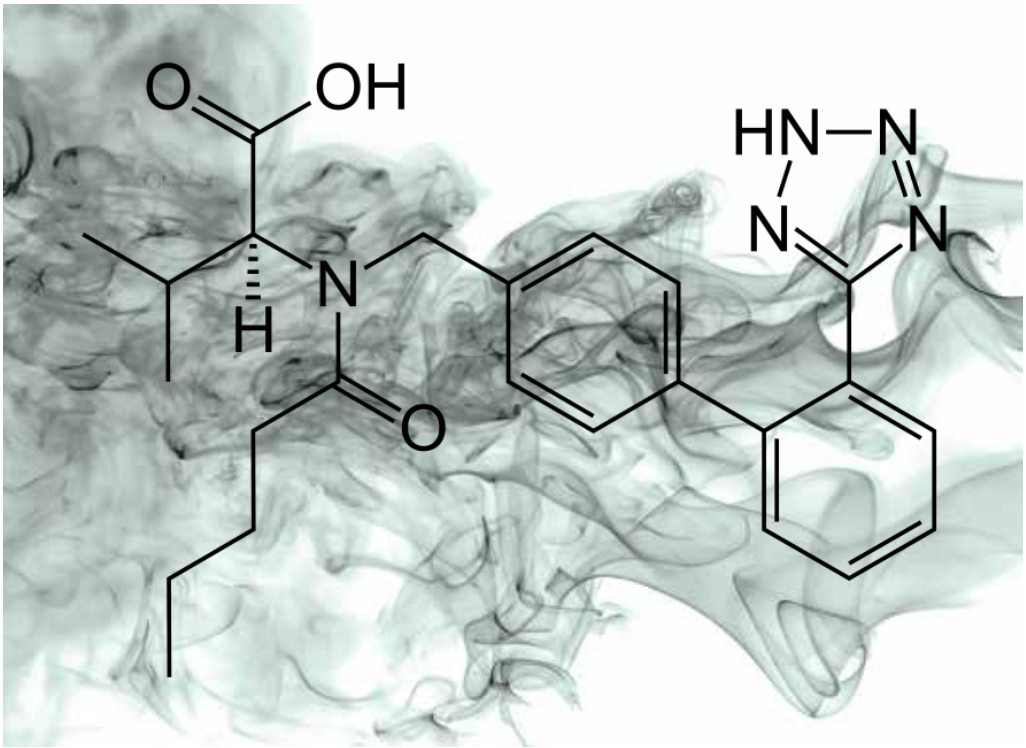
GMP Webinar Series on Impurities – Highlights and Updates

European Pharmacopoeia Activities on Elemental Impurities and Nitrosamines

Date:
Tuesday, 30 June 2020, 14.00 – 15.30 h CEST

Speaker:
Dr Ulrich Rose, EDQM



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

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Background

In September 2019 EMA published documents which request Marketing Authorisation Holders (MAHs) to evaluate the risk of the presence of Nitrosamine impurities in human medicinal products containing chemically synthesised APIs. In case of contamination with Nitrosamines which requires critical changes in the manufacture of drug substances and drug products MAHs have to file a variation application. All regulatory activities with regard to such cases have to be completed within a 3 years period (end of March 2022). Contamination with Elemental Impurities (EIs) in drug products is a critical case as well. The ICH Q3D Guideline outlines PDE values for EIs and requests controls designed to limit their presence in Drug Products to levels at or below the PDE. As both Nitrosamines and EIs are of particular concern in pharmaceutical products European Pharmacopoeia policies had to be amended which led to the revision of a number of monographs. .

Educational Objectives

In this webinar you will get an update of European Pharmacopoeia activities around mutagenic impurities with focus on Nitrosamines and Elemental Impurities. You will be informed about

- how the control of Nitrosamines is reflected in the Ph. Eur.
- the changes in the individual and general monographs of the Ph. Eur.
- what has to be considered regarding the new general chapter on control of nitrosamines
- how ICH Q3D has been implemented in the Ph. Eur.
- the second phase for revision of excipient monographs

A representative of EDQM will explain the recent initiatives with respect to drug substance monographs of the Ph. Eur.

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 Ulrich Rose, EDQM

Dr Ulrich Rose works since 1991 at the EDQM in Strasbourg. Until 2011 he was responsible for establishment and monitoring of the Ph. Eur. reference standards and was involved in the elaboration and revision of monographs of the European Pharmacopoeia. After that he became coordinator and auditor for EDQM's Mutual Joint Audit Program. Since 2014 he is head of division A and deputy head of the European Pharmacopoeia Department where he is overlooking the monograph work on chemically defined APIs, finished products, excipients, herbals and general chapters of Ph. Eur. and is involved in the international harmonisation of pharmacopoeias.

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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Registration for the GMP Webinar "European Pharmacopoeia Activities on Elemental Impurities and Nitrosamines" on Tuesday, 30 June 2020, 14.00 – 15.30 h CEST
Speaker: Dr Ulrich Rose, EDQM
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 noon on 29 June 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

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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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!
German law shall apply. Court of jurisdiction is Heidelberg.