The future Role of Titanium dioxide as an excipient in Pharmaceuticals - Exploring the current and future situation worldwide

14 - 15 September 2022
Brussels, Belgium

Course no. 6911

Hot topic

Target group

This conference is intended for professionals/scientists working in: Research/ Development and Formulation Department, Regulatory Affairs Department, Project Management and QA Department as well as Risk Management Department.

The conference is also intended for members of regulatory authorities.

A joint event of

iPEC EUROPE 30 YRS

IPEC AMERICAS 30 YEARS OF EXCIPIENT LEADERSHIP

IQ INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

APV MAKING SCIENCE WORK

Introduction

Dear Colleagues,

APV is delighted to invite you to our conference on "The future Role of Titanium dioxide (E171, TiO_2) as an excipient in Pharmaceuticals - Exploring the current and future situation worldwide".

The conference will focus on hot topics relating to use and replacement of titanium dioxide as a pharmaceutical excipient. The use of TiO_2 in medicinal products is under scrutiny, raising concerns among pharmaceutical manufacturers about suitable alternatives.

Titanium dioxide is one of the most commonly used pharmaceutical excipients. It is used very often in solid oral dosage forms (e.g. tablets, hard capsules, soft capsules, granules/powder for oral suspensions) and in semi-solid oral dosage forms (e.g. oral paste) as a white pigment or opacifier. Until now, no equivalent alternative is available that has similar properties of titanium dioxide regarding opacity, whiteness, inertness, protection from UV light and surface texture of the resulting medicines.

On May 6, 2021, the European Food Safety Authority (EFSA) published its "Safety assessment of titanium dioxide (E171) as a food additive" expressing several uncertainties related to TiO2 particles, in particular the shape of TiO2 nanoparticles and the potential of these nanoparticles to accumulate in the body and cause immunotoxicity, inflammation, and neurotoxicity as well as other potential effects. EFSA did not conclude that there are any actual safety concerns with TiO2, but rather that, due to some data gaps and uncertainties related to genotoxicity, that they could no longer say that E171 is safe based on the precautionary principle. In view of the present opinion, the European Commission legislated that E171 will no longer be approved for use in food as of 7th of August 2022." Other regulators in the UK and Canada, after thorough scientific evaluations of all the existing data, have concluded that there are no safety concerns with E171 that currently warrant any changes in the use of TiO2 in foods or pharmaceuticals in those countries.

In European Commission Regulation 2022/63 of 14 January 2022 on the use of TiO_2, the Commission states that it will review within three years of the entry into force of this Regulation whether titanium dioxide (E171) needs to be maintained or removed from the Union list of food additives for exclusive use as a colorant in medicinal products in Part B of Annex II to Regulation (EC) No 1333/2008.The European Medicines Agency (EMA) is to perform an assessment of pharmaceutical uses of TiO_2 and the implications of a ban in pharmaceuticals and submit a report to the Commission by April 2024.

The first half day of the conference will focus on the technical use and the role of titanium dioxide in pharmaceutical applications. We will highlight the issues surrounding the use of titanium dioxide and why its use is being questioned. The current legal situation regarding the use of titanium dioxide in pharmaceuticals will be presented from a lawyer's point of view and we will close the day with a discussion panel on the topics presented.

On the second day we will cover the challenges associated with the replacement of titanium dioxide from different perspectives (OTC/RX producers, EU perspective versus global perspective). We will discuss the regulatory perspectives worldwide and how the impact of replacing TiO_2 can be addressed through different types of variations of marketing approvals. Excipient manufacturers are currently developing titanium dioxide-free coating systems and capsules shells with similar pharmaceutical properties to TiO_2. Presentations will be given to explain the latest results regarding the safety of TiO_2 and also the use of calcium carbonate as one of the possible alternatives. A special session will be focussed on the different perspectives on this topic in other parts of the world, i.e.UK , Canada and USA.

We are looking forward to welcoming you

Objectives

The primary goal of the conference is to highlight current hot topics associated with the use and replacement of titanium dioxide as pharmaceutical excipient.

Take the opportunity to share your experiences and discuss with colleagues of pharmaceutical industry, academics, and authorities as well as with manufacturers of pharmaceutical excipients and capsule shell producers. The challenge for the pharmaceuticals industry is that TiO2 has several highly beneficial functions, including opacity, the ability to increase whiteness, prevent light transmission and moisture absorption, as well as stability and protection against degradation. Any changes should be considered on a case-by-case basis and would take significant time, studies resulting in reformulation of the drug product including new stability and compatibility studies and possibly new clinical trials. This could result in a lead time of about 5 to 10 years to develop formulations and generate the new data needed to support registration activities of the thousands of drug products that are currently in late stage development and on the market.

Programme

Wednesday, 14 September 2022, 12:00-18:00 h

Welcome & Introduction
Kevin Hughes, Colorcon Limited, Representative IPEC Europe
Jason Melnick, Eli Lilly and Company, Representative IQ consortium
David R. Schoneker, Black Diamond Regulatory Consulting, LLC, Representative IPEC Americas
Mahmud Yunis, Biogrund GmbH, Representative APV e.V.

Background and history: legal and technical aspects

Overview of TiO_2 – Technical review
- What are the implications and realities of replacing titanium dioxide?
- TiO_2 why has it been used so much?

Mike Tobyn, Bristol-Myers Squibb Pharmaceuticals Limited

History of why we are in this situation now – EU and global situation
Bram Baert, Lonza Group
Kevin Hughes, Colorcon Limited

Overview on the regulatory framework
- Difference between E171 vs. TiO_2
- Why is it 'easier' to remove E171 from food products than from pharmaceuticals?

Michael Weidner, Kozianka & Weidner Rechtsanwälte

Toxicological considerations of TiO2
Thomas Broschard, Merck Healthcare

Panel discussion

Networking dinner

Thursday, 15 September 2022, 08:15-16:15 h

Current and future situation of TiO_2/E171

What is necessary from OTC manufacturers point of view?
Joachim Hermann, Dr. Willmar Schwabe GmbH

What is necessary from OTC/RX mid-size manufacturers point of view?
Hendrik Schütte, Krewel Meuselbach GmbH

What is necessary from RX manufacturers point of view?
Bruno C. Hancock, European Federation of Pharmaceutical Industries and Associations

What is necessary from regulatory affairs point of view?
Guido Holzem, Grünenthal GmbH

Technical challenges from different coating producers' point view
A joint session of several companies - Ashland, Biogrund, Colorcon, JRS Pharma and Seppic
Stevel Misselwitz, Colorcon Limited
Alireza Ramtin, JRS Pharma
Jason Teckoe, Colorcon Limited

Calcium carbonate as alternative
Joachim Orth, Omya International AG, Calcium Carbonate Association Europe

Challenges from a capsules shell producer point of view
Julien Lamps and Ljiljana Palangetic, Lonza Group

Global situation:
- United Kingdom
  Kevin Hughes, Colorcon Limited
- The Global Situation with E171 outside of Europe and the UK - Canada, U.S, Australia/New Zealand, Middle East, MERCOSUR, others
  David R. Schoneker, Black Diamond Regulatory Consulting, LLC

Safety of E171 – status quo
David Lockley, Chair of TDMA CLH Task Force (prerecorded talk)
David R. Schoneker for live Q&A

Panel discussion

Closing remarks

Programme is subject to change

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de

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Location

Pullman Brussels Centre Midi
Place Victor Horta 1
1060 Brussels
Belgium
+32 2 528 98 14
H7431-sb@accor.com

Date

Course no.: 6911
from 14 September 2022 12:00 h
to 15 September 2022 16:30 h

Registration fee

All-day-ticket

Industry	1290 EUR
Authority/University	645 EUR
Students*	200 EUR

(free of VAT according to § 4,22 UStG)
Coffee breaks, luncheons, dinner and electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotelreservation

Pullman Brussels Centre Midi
Place Victor Horta 1
1060 Brussels
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+32 2 528 98 14
H7431-sb@accor.com

Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate of 150€: 25 August. Further we recommend to use booking.com, there are a view more hotels close to the train station Brussels-Midi and the conference hotel.

The future Role of Titanium dioxide as an excipient in Pharmaceuticals, 14-15 September 2022, Brussels, BE, Course no.: 6911

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

☐ By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

☐ I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

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International Association for Pharmaceutical Technology

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