

In this edition...

A new world of excipients for oral solid dosage formulation pages 1 to 3

The word from the chair page 2

Welcome to another new member page 2

News from the IPEC Committees page 4

Committee calendar page 4

Eye on Europe page 5

- Minimising BSE risk in medicines
- Revision of GMP Annex 14
- Vaccine Antigen Master Files
- EMEA work programme for 2009
- GMP/GDP Working Party unveils 2009 priorities
- NIR spectroscopy for pharma
- Clinical data from non-EU trials

At a glance: EU documents for comment page 5

Eye on the World page 6

- FDA publishes ICH Q4B guidance
- Nanotechnology initiative
- USP's glycerin, heparin monographs published

IPEC plans response to globalising drug industry page 6

IPEC guides available for download page 6

Events calendar page 7

Excipient industry news round-up page 7

- Nigeria arraigns three men in tainted syrup case
- Real-time tablet tester debuts at Pittcon

A New World of Excipients for Oral Solid Dosage Formulation



By Liliana Miinea, Jim Farina, Madhu Kallam and Nandu Deorkar

Reproduced courtesy of Pharmaceutical Processing magazine

To meet emerging challenges, the pharmaceutical industry is currently in the midst of reinventing itself. These challenges include continually increasing drug development costs, slowing new product approval, blockbuster drug patent expirations, price pressure and global competition. Concurrently, significant opportunities exist for the industry, including an increasing patient population, numerous unmet medical needs, growing disease awareness, globalization of operations and markets, and advances in efficiency.

The focus on drug development costs is driving the industry to consider outsource-

ing, relocating production and sourcing ingredients from lower-cost locations. These options are being explored to meet the challenge of utilizing a more robust, streamlined and efficient manufacturing process, and to secure a supply chain.

To overcome the challenges of price pressure due to "generitization" of branded drugs, as well as severe global competition, even in the generic sector, many pharmaceutical companies are seeking new proprietary drug delivery formulations. Even companies that specifically make generics are developing alternative, patentable formulations.

Innovative, new excipients offered by various excipient suppliers enable the development of new dosage forms, improve efficiency and may reduce the cost of drugs. Excipients can add functionality to pharmaceutical products. They offer opportunities to introduce new dosage forms, and thus facilitate the extension of patent life. According to market research firm Frost & Sullivan, pharmaceutical companies are recognizing the value of excipients more than ever, particularly when it comes to drug efficacy, safety, stability and storage.

The major classes of solid dosage forms include Immediate Release (IR), Orally Disintegrating Tablets (ODT) and Controlled Release Tablets (CRT). The excipients, along with their manufacturing processes, play a critical role in making desired tablets.

To expedite drug product development, formulators frequently select wet granulation as their manufacturing process. Wet granulation is a process that is less dependent on excipient performance attributes. However, it involves multiple

Cont'd on page 2



The word from the chair

Dear Members,

March 16, 2009

Welcome to the March edition of *Excipients Insight*, which unashamedly comes to you with a springtime theme. It may still be cold but - at least where I am sitting - signs that winter is drawing to a close are all around.

As nature bursts into life around us we are also witnessing the birth of a new IPEC, one that has a worldwide focus and the perspective to bring our industry forward in step with the rapid globalization of the pharmaceutical sector.



additional IPECs will be formed in Latin America and India.

And as IPEC welcomes new regions into its fold, I'm happy to say that IPEC Europe is also continuing to expand. The latest company to join our ranks is Procter & Gamble (see below), and I look forward to welcoming the company's representatives at future IPEC meetings and events.

Finally, you may also notice some subtle changes to this edition of our newsletter. We have adopted a new font and made some style changes in an effort to enhance readability. Please let us have your feedback on that and of course any suggestions for further improvements.

Public health tragedies related to the security of excipient supply continue to be reported (for the latest update on the case in Nigeria see page 7), and it is more important than ever that IPEC is positioned to provide advocacy and promote quality in excipients around the world.

On page 6 of this edition you can read about the proposed metamorphosis of TriPEEC into a new structure - to be called the IPEC Federation.

We will shortly issue a press release setting out the vision and mission of the IPEC Federation, and of course welcome your comments on this pivotal project.

The creation of IPEC China last year was a fantastic and timely achievement, but made it clear that TriPEEC needed to expand its horizons to include emerging pharmaceutical markets. This has become doubly apparent with the possibility that

On behalf of the IPEC Europe Board,

Patricia Rafidison

Chair to IPEC Europe



A New World of Excipients for Oral Solid Dosage Formulation

(Cont'd)



manufacturing steps, which can add time and cost to the development process. Conversely, Direct Compression (DC) is becoming a preferred manufacturing process as the continually modernizing pharmaceutical industry strives to improve its manufacturing cost and productivity.

DC requires the selection of excipients with the physical characteristics that increase flowability and compressibility of the tableting blend. Utilizing high-speed tableting machines, DC enables the rapid production of high-quality tablets. Along with the Active Pharmaceutical Ingredient (API), the tableting blend also frequently contains a filler, binder, disintegrant, auxiliary excipients (glidants, solubilizers etc.) and a lubricant. The physical properties of these powder mixtures are often hard to predict. Problems can appear due to differences in particle size distribution of various components, uniformity of blending and segregation issues, among others. Tableting parameters, such as equipment geometry and energy input, can add to the complexity of the process when working with multi-particulate powder systems.

Modern excipients are engineered to possess the properties of key components of the tableting blend in a single, highly flowable and compressible granular material. This material can provide a way to achieve a DC blend consisting of the API, the "engineered" excipient and the lubricant, which can be successfully used in a high-speed tableting machine.

Recent development in the excipient field, particularly in the area of performance excipients for DC, with applications in IR, ODT and CRT, are reviewed in this article.

The Latest Developments in the Excipients Marketplace

As the pharmaceutical industry strives to improve manufacturing processes, reduce costs and differentiate drug products, excipient suppliers are encouraged to provide novel excipients.

A survey by Shangraw and Demarest within the pharmaceutical industry ranked microcrystalline cellulose (MCC) as the most useful filler/binder for direct compression. MCC also has some disintegrant and anti-adherent properties. MCC has grown in popularity due to its excellent compactibility at low pressures and high-dilution potential. Presently available, there are already many MCC-based, co-processed excipients. These co-processed excipients improve functional properties such as the compressibility and flowability

Cont'd on page 3

New IPEC member

IPEC Europe is delighted to welcome another new member company this month.

Procter & Gamble is one of the world's leading consumer goods companies. The group employs 138,000 employees in over 80 countries worldwide. Its European business dates back to 1930 when the company opened a subsidiary in the UK.



Today, P&G has a presence in every country in Western Europe and the region represents about a quarter of their total business.

Main contact: Syindee Lee at lee.sd@pg.com; tel: +41-58-004.51.52

A New World of Excipients for

Oral Solid Dosage Formulation

(Cont'd)



of MCC. Others improve functionality as a result of the incorporation of silica into the MCC matrix.

Mallinckrodt Baker has recently launched a novel performance excipient product - PanExcea™ MHC300G - based on particle engineering technology. This performance excipient is a composite particle of MCC (filler); hydroxypropyl methylcellulose (HPMC; binder) and crospovidone (CPVD; disintegrant). PanExcea MHC300G is specifically developed for immediate release tableting by direct compression in high-speed tableting machines. It is engineered to provide unique spherical particle morphology, porosity and surface activity for significantly improved flowability, compressibility, API mixing capabilities and consistent disintegration. The performance excipient allows for immediate release tablet production simply using the API and this excipient in combination, or by dilution with other auxiliary excipients. Another type of direct compression excipient currently on the market consists of lactose monohydrate, poly (vinylpyrrolidone) and crospovidone.

A series of new performance excipients were specifically designed for use in oral disintegrant tablet formulations. These excipients contribute to the manufacture and function of cost-effective, orally disintegrating drug products by DC as compared to specialized technologies such as freeze drying or tablet molding. ODT performance excipients offer properties that are not achieved from simply blending the individual ingredients. They impart sufficient hardness to tablets with low friability and demonstrate buccal disintegration times within 30 seconds, without water. Mallinckrodt Baker's PanExcea ODT performance excipient enables good taste and texture, along with fast dispersibility as a result of its particle engineering technology.

Simultaneously, manufacturers are also targeting excipients to improve the performance of controlled-release formulations, enable faster development and easy manufacturing. Though many controlled release technologies have emerged, few co-processed excipients exist that can be used for direct compression of extended release tablets. For example, Dow Wolff Cellulosics has introduced two new hypromellose products for direct compression of controlled-release matrix oral dosage forms.

Increasing numbers of drug candidates are not water soluble and therefore require specialized formulations in order to fulfill their potential. Biological drugs, such as peptides, proteins and monoclonal anti-

bodies are posing significant challenges for oral formulations. Poor membrane permeability, enzymatic instability, large molecular size and hydrophilic properties are all factors that have provided major hurdles for peptide and protein formulations. However, these challenges present opportunities for the development of new and novel excipients. These development activities require collaborative efforts by excipient manufacturers and the pharmaceutical industry to overcome development costs and regulatory hurdles.



Role of Excipients in Quality by Design

The systematic drug product development approach, known as Quality by Design (QbD), is at the heart of the U.S. Food and Drug Administration's (FDA) expectations for new pharmaceutical development applications.

QbD involves the following key elements:

- ▣ Target the product profile;
- ▣ Determine critical quality attributes (CQAs);
- ▣ Link raw material attributes and process parameters to CQAs and perform risk assessment;
- ▣ Develop a design space;
- ▣ Design and implement a control strategy; and
- ▣ Manage product life cycle, including continual improvement.

CQAs are the characteristics of the final product that should remain within certain limits in order for Quality Assurance to approve the release of the product. Linking raw material attributes to CQAs is a valuable science-based process that can aid in identifying which material attributes and process parameters critically affect product CQAs. This linkage forms the basis for defining design space. The excipients, having defined physical characteristics and functionalities, can help implement QbD

principles by simplifying the dimensions of the design space. Similarly, new excipients can be developed utilizing QbD principles, thereby linking product physical or chemical characteristics to the performance attributes. As such, novel excipients designed to offer consistent desired performance and quality could further ease implementation of QbD for drug products providing benefits to pharmaceutical industry and patients.

Selection and Qualification of Novel Excipients and Excipient Suppliers

Novel excipients are used in formulations due to their unique properties. They are developed through a unique combination process of commonly known excipients. Under this new combination, the excipients provide different physical properties that deliver desired functionalities such as powder flow, compressibility, API blendability and tablet disintegration. This route enables ease of regulatory approval and lower development costs, while ensuring faster time to market, when compared to developing chemically new excipients.

As the role of excipients is to improve the stability of the finished drug product, it is vital to ensure the excipient is not a potential source of impurities, such as degradation products, heavy metals, microbiological contaminants, process related impurities and residual solvents. As such, the excipient should be well characterized and manufactured under appropriate regulatory framework and guidelines. Although there are no specific globally consistent Good Manufacturing Practice (GMP) regulations for excipients, they must be manufactured utilizing GMP principles. Due to change in the global environment and focus on excipients, various regulatory guidelines and proposals have emerged.

The International Pharmaceutical Excipient Council (IPEC) has published GMP guidelines for excipients. Excipient manufacturers should follow these guidelines and have effective quality systems and process controls to provide consistent, quality products. In addition, supplier audits should be an overall part of excipient supplier qualification. IPEC has published excipient qualification guidelines.

Since most novel excipients may be proprietary in nature, the excipient supplier qualification should also include an evaluation of supply chain risk/safety and contingency plans, as well as supply and quality agreements. In addition, the supplier must be able to provide regulatory support beyond the drug master file, which enables seamless incorporation and approval of drug products by appropriate authorities, such as the US FDA.

Article reproduced from Pharmaceutical Processing magazine (March issue) with grateful thanks. Please visit the following link for full bibliography and author details. (<http://tinyurl.com/bwrl43>)

News from the IPEC committees



The minutes of past committee meetings are available on the members area of IPEC Europe's website. If you are interested in joining any of them or participating in some of their activities please contact the chairs:

- GMP Committee: [Iain Moore](#)
- Regulatory Affairs Committee: [Carl Mroz](#)
- Harmonization Committee: [George Mansveld](#), or the vice-chair [Bernhard Fussnegger](#)
- GDP Committee: [Frank Milek](#).



Good Manufacturing Practice

Certification: The certification project continues with much effort being put into the various task forces. We now have a Global Steering Committee which includes all partners. The excipient classification team has been combined with the GMP team so that they can work in tandem on this topic.

Several teleconferences and webinars have been organised and a meeting in Darmstadt is planned for 24 April. A web-based survey of the membership of the participating organisations has taken place - thanks for your contributions - analysis of the replies is ongoing. The GDP team has begun planning its efforts and aims to have a draft available for late April as well.

We are now starting up the auditor competency task force and will shortly be asking for volunteers in this critical part of the project. A stakeholders meeting is planned for 14 May at which we intend to present the plans in some detail to key user, supplier and regulatory bodies.

Excipient Information Package: This has been issued for final review by committee members. Please submit any comments as soon as possible. The document will then be revised as needed and submitted to the boards for approval to publish. The Quality Agreement Guide is also undergoing the same process.

Significant Change Guide: Work has started on some proposals to revise the IPEC-Americas Significant Change Guide, but as a result of complications arising from the previous version's publication in the USP IPEC-Americas will now update and reissue their guide. Work on a harmonised international guide will then commence. Suggestions for alterations have already been made by the European team.

Stability Guide: The Stability Guide has been updated by the European team and passed back to IPEC-Americas for their comments. We would hope to conclude this quite quickly now.



Regulatory Affairs

Quality by Design: The committee organised a brainstorming meeting on March 5 in Brussels, led by Ulla Paulsen-Sörman (AstraZeneca), and Carl Mroz (Colorcon).

The meeting gave an opportunity to open up a preliminary set of discussions between users and manufacturers on this

fast-emerging topic, to help understand each other perspectives, identify potential gaps, and identify the expectations of regulators.

An update on the deliberations will be published in the April edition of *Excipients Insight*.

Committee Calendar

| | | | | |
|-----------------------------------|------------------------|--------------------------------------|--------------------------|---------------------|
| Harmonisation | 16 April Brussels | 8 July Strasbourg or Darmstadt | 28 October Brussels | |
| GDP | 21 April Manchester | 23 June Hamburg | 4 September Stuttgart | 5 November Stade |
| Joint GMP / Regulatory Affairs | 21 April Brussels | 21 October Brussels | | |



Eye on Europe



Minimising BSE risk in medicines

The European Commission (DG Enterprise and Industry) has published a [Note for Guidance](#) on minimising the risk of transmitting bovine spongiform encephalopathy (BSE) agents via human and veterinary medicinal product.

The consultation on the draft revision of this guidance has been implemented to take into account advancement of science in the area of transmissible encephalopathies, as well as the evolving situation regarding BSE across the world, said the EC.

New criteria for the sourcing and processing of gelatin and bovine blood derivatives used in the manufacture of medicinal products for human or veterinary use are introduced, as well as a new subsection on peptones. The guidance also covers materials derived from TSE-relevant animal species used in the preparation of excipients and adjuvants.

The Benefit/Risk Evaluation paragraph mentions that "*high-infectivity tissues (Category IA tissues) and substances derived thereof shall not be used in manufacture of medicinal products, their starting materials and intermediate products (including active substances, excipients and reagents), unless justified. A justification why no other materials can be used shall be provided.*"

Revision of Annex 14

The EC has also launched a public consultation on a revision of [Annex 14](#) of the GMP Guide (Manufacture of medicinal products derived from human blood or plasma). This annex has been revised in light of legislation setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

Constituents of the excipient must be provided in the Plasma Master File. Provisions for certain excipients, expected to be defined in accordance with Article 46(f) of Dir. 2001/83/EC, are also foreseen. [Comments](#) by 31 July.

Vaccine Antigen Master File

The Commission has revised [Annex I to Dir. 2001/82/EC](#) to simplify the procedures for the assessment of veterinary vaccines, introducing a Vaccine Antigen Master File and the concept of multi-strain dossier. Member States have to bring this directive into force by 3 September.

The paragraph related to 'control of starting material' makes clear reference to the Certificate of Suitability issued by the EDQM for a starting material, active substance or excipient, referencing the relevant monographs of the European Pharmacopoeia.



EMA work programme for 2009

The European Medicines Agency's [work plan for 2009](#) will focus on improving the effectiveness and efficiency of its core activities, with a particular emphasis on international strategy in the light of global challenges. Other targets include:

- ▶ strengthening the EU medicines network; boosting the safety monitoring of medicines;
- ▶ introducing new legislation on advanced therapy medicinal products for human use;
- ▶ fostering transparency, communication and provision of information;
- ▶ contributing to improved availability of medicines; and
- ▶ "contributing to an environment that stimulates innovation."

Of particular interest for excipients is the intention of the CVMP's Safety Working Party to develop a reflection paper/guideline, along with the EC, to address how to approach the issue of pharmacological activity of excipients.

GMP/GDP work plan

Highlights of the GMP/GDP Inspectors Working Group [work plan](#) for 2009 include:

- ▶ amending chapters 3 and 5 of the GMP Guide on 'dedicated facilities';
- ▶ amending chapter 5 of the GMP Guide on 'qualification of suppliers and testing of starting materials';
- ▶ revising GDP guidance to consider proposals to fight counterfeits; and
- ▶ working in collaboration with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme.

The WP will also monitor the development of ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System), and the ICH Quality Implementation Group.

NIR Spectroscopy for pharma

The CHMP/CVMP has published a [draft guideline](#) that will replace the current [Note for Guidance](#) on the use of near infrared spectroscopy by the pharmaceutical industry.

The new guideline is more detailed than its predecessor and aims to clarify and differentiate the data requirements for the marketing authorisation dossier and those for GMP, including change control. NIRS has become a well established technique and has been used for several years in the pharmaceutical industry for the identification and assay of pharmaceutical starting materials, intermediates and finished products, as well as for in-process control and monitoring purposes. It is one of the major methods in Process Analytical Technologies (PAT).

NIRS also applies to excipients. When preparing the representative sample population for a quantitative or a qualitative method, the variations in the matrix for excipients have to be included in the list of potential variants that may be encountered in routine production. The draft is open for [comment](#) until 31 August.

Clinical data from non-EU trials

The EMEA has published a [reflection paper](#) on "the need to understand the differences and concerns that may arise in the extrapolation of study results to the EU population." ICH E5 guideline already identifies extrinsic factors to be considered, when deciding whether trials performed outside the EU are applicable or if further studies should be performed within the EU. For comment by end of May.

The agency has also published a [strategy paper](#) on the topic of acceptance of clinical trials performed in third countries.

| EU documents released for comment | Deadline (2009) |
|---|-----------------|
| Extrapolation clinical studies for the EU (EMA) | 31 May |
| Minimising risk for BSE (EC, and EMA) | 30 June |
| Eudralex Vol. 4 GMP - Annex 14 (EC) | 31 July |
| Use of infrared spectroscopy (EMA) | 31 August |





Eye on the World



FDA publishes ICH Q4B guidance

The FDA has published Annexes 6, 7 and 8, which respectively represent general chapters on [uniformity of dosage units](#), [dissolution tests](#), and [sterility tests](#), of the ICH Q4B 'Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions'. Stakeholders from ICH regions are encouraged to submit their comments to their respective Regulatory Authorities. Considerations for implementation in the different ICH regions are also provided in the annexes.

Nanotechnology initiative

The FDA also unveiled an [initiative](#) with the Alliance for NanoHealth (ANH) to speed the development of safe and effective medical products in the field of nanotechnology. The initiative will work to expand knowledge of how nanoparticles behave and affect biologic systems, and to develop tests and processes that might mitigate risks associated with nanoengineered products.



USP's glycerin, heparin monographs

► Glycerin monograph

The monograph published in March 2008 has been revised to take industry comments into consideration, in particular on identification tests A, B, and C, and the revision of the limit of diethylene glycol and related compounds. The revision will become official on 1 May. More information [here](#).

► Heparin monograph

Following the contaminated heparin incident, revised monographs for [heparin sodium](#) and [heparin calcium](#) were published in June 2008. The USP Heparin Advisory Panel provided further recommendations on [heparin sodium](#) and [heparin sodium injection](#) on identification tests, potency, organic impurities, absence of OSCS and four new USP reference standards. Comments can be provided by 15 May 2009. The new heparin monographs will then become official on 1 August 2009.

IPEC plans response to globalising drug industry

With the pharmaceutical sector increasingly operating on a global scale, supply chains for sourcing excipients are becoming more complex, and the risk of errors caused by mislabelling, contamination or substitution of one substance for another is increasing.

In recognition of this the International Pharmaceutical Excipients Council (IPEC) has responded with a proposal to create its own multi-regional body - to be called the IPEC Federation - that will provide advocacy and promote quality in excipients around the world.

"Public health tragedies related to the security of excipient supply continue to be reported, so it is more important than ever that IPEC is positioned to provide advocacy and promote quality in excipients around the world," commented Patricia Rafidison, chair of IPEC Europe.

"It is envisaged that additional national or regional IPECs will be formed to ensure that excipient issues are voiced globally," she added.

A complete statement will be made available to IPEC members in the near future, but in the meantime the key elements are as follows:

The **vision** of IPEC Federation would be to promote quality, safety and functionality of excipients worldwide in support of self-regulation, and ensure that new excipients introduced onto the market are safe and meet global standards. It will seek to harmonize drug approval, technical and pharmacopoeial standards and ensure safe and effective finished drug dosage forms circulate throughout the global supply chain.

The **mission** of IPEC Federation would be to develop, implement, and promote voluntary, harmonised guidance and other programmes for the pharmaceutical industry designed to ensure that excipients used in finished drug products meet appropriate standards for quality, safety, and functionality throughout their manufacturing and distribution processes. It will collaborate with and help regulatory authorities in adopting scientifically suitable, risk-based and valid global regulatory and compendial standards for excipients.

The plan is to launch the IPEC Federation at the next planned meeting in June 2009 at Yokohama, Japan.

Download your IPEC Guides here...

2008 Qualification of Excipient for Pharmaceutical Use

- Download Word format
- Download PDF format

2008 The IPEC-PQG Good Manufacturing Practices Audit Guideline

- Download Word format
- Download PDF format

2008 The IPEC Good Distribution Practices Audit Guideline

- Download Word format
- Download PDF format

2006 The IPEC-PQG Good Manufacturing Practices Guideline

- Download PDF format

2006 The IPEC Good Distribution Practices Guideline

- Download PDF format

Events Calendar



- FECC seminar Quality standards in the supply chain of pharmaceutical, food, feed and cosmetic ingredients**
Brussels/Belgium, 19 March
More information [here](#).
Programme available [here](#).
- Seminar on GMP for Excipients**
Heidelberg/Germany, 24 March
More information [here](#).
- Pharmaceutical Forum: delivering for patients**
Brussels/Belgium, 25 March
More information [here](#).
- ISPE Conference on Enhanced Competitiveness**
Brussels, Belgium, 2 April
More information [here](#).
- EMEA/EFPIA 2nd workshop on Adaptive Design in Confirmatory Trials**
London/UK, 2 April
More information [here](#).
- EMEA First Workshop on Advanced Therapy Medicinal products (ATMP)**
London/UK, 3 April
More information [here](#).
- 5th Annual Global Pharmaceutical Conference - Current worldwide regulatory and compendial expectations: impact on laboratory operations**
Frankfurt/Germany, 22-24 April
More information [here](#).
- EFCG 4th Pharma Business Conference**
Brussels/Belgium, 13-14 May
More information [here](#).
- PharmSciFair**
Nice/France, 8-12 June
Second announcement is available [here](#).
Note also that a pre-satellite meeting dedicated to young scientist will be held on 7-8 June (more information [here](#))
- Paediatric drug development - tackling current and future challenges**
Saint-Rémy de Provence/France, 17-20 June
More information [here](#).

Excipient industry news round-up



Like to see your news featured here?
Send your releases to info@ipec-europe.org.

Nigerian court arraigns men in tainted teething syrup case

Three men have been arraigned in a Federal High Court in Lagos, Nigeria, charged with deliberately adulterating a teething syrup product and causing the deaths of more than 80 infants.

Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), which is bringing the case, says that 84 children died in 2008 after being administered Barewa Pharmaceuticals' My Pikin paracetamol-based teething syrup before it was later withdrawn from the market. Several other children who received the product subsequently suffered adverse reactions including fever, convulsions, diarrhoea, and kidney failure.

The cause of the deaths is believed to be diethylene glycol (DEG) which has been linked to hundreds of deaths worldwide in the last 20 years.

An incident in Panama in 2006 saw 21 people die after taking a cough syrup made with DEG that had been mislabelled as glycerin, a widely-used excipient. A similar case involving DEG in cough syrup in 1996 led to the deaths of 88 people in Haiti, while in 1990-1992 paracetamol syrup in which DEG was substituted for propylene glycol caused 236 deaths in India and Bangladesh.

And Nigeria also has another serious example in its history books. In 1990, 47 people died in the country after taking a cough syrup contaminated with solvents.

In the latest case, Kola Gbadegbesin Okunlola, the chief executive of Barewa has been charged with "intent to cause death or grievous bodily harm to members of the public."

The court must determine whether the DEG got into the teething syrup as a result of mislabelling, contamination or deliberate substitution of one substance for another.

Okunlola pleaded not guilty to the charges at the hearing on 2 March, as did two other company officials, Adeyemo Abiodun and Egbele Austine Eromosele. If convicted, the defendants are facing a jail term of between five and 15 years and a possible fine. The NAFDAC's director-general, Paul Orhii, said last month that the agency is seeking the maximum penalty.

The presiding judge in the case, Justice Okechukwu Okeke, has adjourned the case until May 4.

This article has been reproduced with kind permission from SecuringPharma.com.

Real-time tablet tester debuts at Pittcon

Using the new ActiPix Dissolution Imager from UK firm Paraytec - formulation scientists are able to 'visualise' - in real-time - what is happening at a tablet surface during the process of dissolution.

The imager was officially introduced at Pittcon on 9 March.

To date only high cost, complex to use techniques such as Terahertz spectroscopic Imaging and Magnetic Resonance Imaging (MRI) have been able to solicit the data to enable formulation scientists to understand complex pharmaceutical drug release processes, claims Paraytec.

The ActiPix Dissolution Imager overcomes these limitations and provides for the first time a truly affordable dissolution imaging capability that does not require expert operation, adds the company.

More information is available [here](#).

IPEC Europe

Supporting the interests of pharmaceutical excipient developers, producers, distributors and users

IPEC Europe
9, Avenue des Gaulois
B-1040 Brussels
Belgium

Tel: +32 2 736 53 54
Fax: +32 2 732 34 27
Email: info@ipec-europe.org

Editor: Phil Taylor

Tel: +44 1527 835 437
Email: pjtcomms@online.rednet.co.uk

Excipients Insight is produced for IPEC Europe by PJT Communications



www.ipec-europe.org