

## Mayuka Labs R&D Centre gets DSIR Recognition

New Delhi based Mayuka Labs Private Limited has received recognition for its in-house research & development facility from the Department of Scientific and Industrial Research (DSIR) under the Ministry of Science and Technology, Government of India.

With this accreditation, Mayuka Labs is entitled to receive support from government establishments such as Council of Scientific & Industrial Research (CSIR), Department of Biotechnology (DBT) and the Department of Science and Technology (DST) for its projects.

According to the DSIR website there are only 1247 companies across all industries, including research labs set up by multi national companies which are recognized by DSIR in India. Within the pharma and biotech space, there are less than 200. Mayuka Labs is now a part of this select group.

## Guardian launches X-tra Vital food supplements

[www.pharmabiz.com](http://www.pharmabiz.com)

Guardian, India's fastest growing retail chain of health, wellness and beauty stores has announced the launch of Guardian X-tra Vital for Men and Women in its Guardian Health Care range of private labels.

Guardian X-tra Vital for Men is multivitamin and mineral capsules, a comprehensive daily food supplement and is fortified with extra ginseng. Traditionally ginseng has been used all over the world to enhance vitality and to counter fatigue and stress.

Guardian X-tra Vital for Women is a comprehensive daily food supplement enriched with multivitamins and minerals. The product is fortified with extra iron, calcium and ginseng. Goes without saying that women have an enhanced need of calcium and iron and the availability of extra ginseng in X-tra Vital helps to counter effects of stress and improves energy levels.

## SiliCycle launches leach-proof catalysts

[www.in-pharmatechnologist.com](http://www.in-pharmatechnologist.com)

Canada-based SiliCycle has launched its heterogeneous leach-proof metal catalysts, which it claims can make green chemistry principles a reality for pharma.

The new SiliaCat catalysts are highly reactive and recyclable, do not require metal leaching and produce better yields than currently available alternatives.

Development of the SiliaCat catalysts took place in conjunction with Mario Pagliaro's Lab at Italy's National Research Council, which set out to apply nanochemistry principles to chemical synthesis.

Current catalysts for cross-coupling reactions such as Suzuki and Sonogashira generally require a homogenous metal catalyst and ligand. However, these reactions suffer from limited reusability and require the user to remove residual metal catalysts, which can be a complex process

## Formulation developed to stop vaccine freeze damage

[www.in-pharmatechnologist.com](http://www.in-pharmatechnologist.com)

Health charity PATH has developed a formulation to stop vaccines suffering from freeze damage, which it believes will help ensure products are fully potent when they reach their destination.

By adding a small amount of freeze-protection stabilisers, such as glycerin, polyethylene glycol 300, or propylene glycol, to vaccines containing aluminium adjuvants damage from freezing was prevented.

The freeze-protection stabilisers have previously safely been used in human medications and PATH believes they can also be applied to vaccines for hepatitis B, diphtheria, tetanus toxoid and pertussis.

## REGULATORY UPDATES

### Drugs and Cosmetics (First Amendment) Rules, 2009

Ministry Of Health And Family Welfare  
(Department of Health)

#### NOTIFICATION

New Delhi, the 22<sup>nd</sup> January, 2009

**\*G.S.R. 45(E).**- The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, after consultation with the Drugs Technical Advisory Board, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said sections, of the said Act, for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of thirty days from the date on which the copies

of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110011;

Any objection or suggestion which may be received from any person with respect to the said draft rules, before the expiry of the period as specified above, will be taken into consideration by the Central Government.

#### DRAFT RULES

1. (1) These rules may be called the **Drugs and Cosmetics (First Amendment) Rules, 2009.**

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in rule 3A, for sub-rule (3), the following sub-rule shall be substituted, namely :-

"(3) The functions of the laboratory in respect of testing of condoms shall be carried out at the Central Drugs Testing Laboratory, Chennai, and the functions of the Director in respect of the said products shall be exercised by the Director of the said Laboratory."

[No. X-11014/3/2008-DFQC]  
DEBASISH PANDA, Jt. Secy.

## US FDA Opens office in India

The US Food and Drug Administration (USFDA) opened its offices in New Delhi and Mumbai in a bid to provide greater protection to consumers.

The office would facilitate to expedite USFDA's process of giving approvals to medicines from Indian drug makers sold in the US.

"Through these offices, we can work more closely with manufacturers to share best practices and ensure producers build quality and safety into food and medical products," US Health and Human Services Secretary Mike Leavitt said.

As part of its Beyond Our Borders Initiative, the US department will send its 10 USFDA officials to India, besides 14 other locations around the world including China, Europe and Latin America.

These officials would conduct inspections of facilities that export medicines to the US and work with the Indian government and the

pharmaceutical industry to develop certification programmes to further enhance trading relationships between the two countries.

At present, USFDA officials visit India to inspect facilities of companies who export medicines to the US.

While USFDA offices in the country would mean fast approvals for Indian drug makers, this may also bring in stricter and more frequent inspections of their facilities.

## US FDA nod for Takeda's dexlansoprazole capsules for GERD

[www.pharmabiz.com](http://www.pharmabiz.com)

The US FDA has approved Kapidex (dexlansoprazole) delayed release capsules for the once-daily, oral treatment of heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD), the healing of erosive esophagitis (EE) and the maintenance of healed EE. Kapidex (30 mg and 60 mg) is the first proton pump inhibitor (PPI) with a Dual Delayed Release (DDR) formulation designed to provide two separate releases of medication.

PPIs reduce acid production by turning off many of the acid pumps in the stomach. Kapidex contains two types of enteric-coated granules resulting in a concentration-time profile with two distinct peaks: the first peak occurs one to two hours after administration, followed by a second peak within four to five hours. In addition, Kapidex can be taken regardless of when food is consumed.

## FDA Approves RiaSTAP for Treatment of Bleeding in Patients with Rare Genetic Defect

[www.fda.gov](http://www.fda.gov)

The US FDA has licensed RiaSTAP, an orphan drug for the treatment of bleeding in patients with a rare genetic defect known as congenital fibrinogen deficiency. Without treatment, these patients are at risk of potentially life-threatening bleeding.

Fibrinogen is manufactured in the liver and circulates in the blood plasma in a normal concentration of 250-400 mg/dL.

Fibrinogen deficiency affects only 150 to 300 people in the United States and is usually diagnosed at birth when newborns bleed from their umbilical cord site. Children with the defect need to curtail activities because of risk of bleeding from minor trauma.

## Unbranded generic drugs to be sold at people's shop

[www.drugscontrol.org](http://www.drugscontrol.org)

The Centre is planning to open 40 Jan Aushadhi shops, (peoples' medicine shops) all over the country by March 4 where generic medicines will be sold at half the price of branded medicines.

A few Jan Aushadhi outlets have already begun functioning in Punjab. The first such store was opened in Amritsar on November 25 last year, as part of a campaign begun by the newly created department of pharmaceuticals under the ministry of chemicals and fertilizers. Following Punjab government's cooperation with the Centre, other states like Haryana, Rajasthan, Bihar and Assam are also coming forward to set up Jan Aushadhi outlets, for which they have to provide space free of cost, preferably in a government hospital.

## Addendum to Indian Pharmacopoeia 2007 comes into Force

[www.drugscontrol.org](http://www.drugscontrol.org)

In a major step towards assuring the health care professionals patients and consumers of the standards of drug in India the Secretary, Ministry of Health & Family Welfare, Shri Naresh Dayal who is also the Chairman of Indian Pharmacopoeia Commission released the Addendum 2008 to the Indian Pharmacopoeia (IP) 2007. The Addendum contains amendments to IP 2007 and adds 73 new monographs on different therapeutic groups representing synthetic, herbals and biological drugs. While the amendments to the IP 2007 will come into force with immediate effect, the new monographs will become effective from 1<sup>st</sup> July 2009.

## DCGI office fails to complete nationwide survey of counterfeit drugs after one year

[www.pharmabiz.com](http://www.pharmabiz.com)

The Union Health Ministry's ambitious nationwide survey to get firsthand authentic report of the extent of counterfeit drugs in the country is learnt to have become a damp squib. As against the target of collecting 31,000 samples, it could collect only around 23,000 samples. The DCGI office may continue the survey in the second phase to meet the target. The much-delayed survey was originally to begin on December 1, 2007. But due to several reasons, including the

department's preoccupation with the fixed dose combination (FDC) drugs issue, the launch was got delayed by almost one year.

All the four zones failed to draw the targeted 7750 samples.

## FDA wants standardised drug pack numbering

[www.in-pharmatechnologist.com](http://www.in-pharmatechnologist.com)

The FDA is calling for all drugs to be labelled using a standardised numerical identifier (SNI) in a bid to tighten up supply chain security.

The proposal is that all packages should be marked with an SNI made up of a National Drug Code (NDC), as set out in the US FDA's 21 CFR part 207, and a unique, 8-digit serial number generated by the manufacturer or re-packer.

Another feature on the guidance is its compatibility with the serialised Global Trade Item Number (sGTIN) model set up by the international standards organisation GS1. The FDA has been a key collaborator on the sGTIN system which, to date, has been adopted by 65 countries as a way of tracking pharmaceuticals.

## Labeling Changes are made for Cosmetics

[www.drugscontrol.org](http://www.drugscontrol.org)

The Ministry of Health and Family Welfare, New Delhi has made certain amendments for labeling of the Cosmetics under Rules.

Now, the Cosmetics will also bear "Use Before" in month & year and will give list of ingredients present in the cosmetic.

The statement of ingredients need not appear on packs of less than 60 ml of liquids and 30 gm of solid/semi Solids.

Cosmetics will also comply with the labeling requirements, if any, specified in BIS standards covered under Schedule S.

A provision is also inserted to prohibit false or misleading claims under Rule 148-B.

## Drugs and Cosmetics

**(First Amendment) Rules, 2009  
MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health)**

### NOTIFICATION

New Delhi, the 22<sup>nd</sup> January, 2009

**\*G.S.R. 46 (E).**- Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs

and Cosmetics Act, 1940 (23 of 1940), vide the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), No. G.S.R. 636(E) dated the 13<sup>th</sup> October, 2006 in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i) dated the 13<sup>th</sup> October, 2006 for inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And, whereas, copies of the said Gazette were made available to the public on 20-10-2006;

And, whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. 1) These rules may be called the **Drugs and Cosmetics (First Amendment) Rules, 2009**.  
(2) They shall come into force after six months from the date of their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, in rule 148, -
  - (a) (i) in sub-rule (1), after the clause (b) the following clause shall be inserted, namely :-  
"(c) use before.....(month and year)".
  - (ii) after sub-rule (6), the following sub-rules shall be inserted, namely :-  
"(7) The list of ingredients, present in concentration of more than one per cent shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one per cent, in any order, and preceded by the words 'INGREDIENTS' :

Provided that this statement need not appear for packs of less than 60 ml of liquids and 30 gm of solid and semi solids.

- (8) Labeling requirements, if any, specified in the relevant Indian Standards laid down by the Bureau of Indian Standards for the cosmetics covered under

Schedule "S".

- (b) after rule 148-A, the following rule shall be inserted, namely :-

**"148-B. Prohibition against false or misleading claims :-** No cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user."

[F. No. X-11014/5/2005-DFQC]  
DEBASISH PANDA, Jt. Secy.

**Foot Note:-**The principle rules were published in the Official Gazette vide notification No. F.-28-10/45/(1), dated 21<sup>st</sup> December, 1945 and were last amended vide notification No. G.S.R. 780(E) dated the 10th November, 2008.

## BUSINESS VENTURES

### Holoflex ties pact with Kezzler to provide anti-counterfeiting services

[www.pharmabiz.com](http://www.pharmabiz.com)

Holoflex of India and Kezzler AS of Norway have signed an agreement for exclusive collaboration in anti-counterfeiting and brand protection services. The Kezzler technology directly empowers consumers to verify the authenticity of their purchase by sending a simple code via SMS. Only genuine products will contain an authentic code, which will be verified by the SMS bounce-back message.

The agreement with Holoflex now allows brand owners to use the Kezzler technology in conjunction with holograms and other types of security labels.

### Rem gets into bed with PsyPharma for sleep studies

[www.outsourcing-pharma.com](http://www.outsourcing-pharma.com)

Two US companies specialising in sleep disorders - Rem Medical and PsyPharma Global, have pooled their resources to offer research services to the pharmaceutical industry.

Rem Medical's primary business is in the running of sleep disorder clinics. Now, with the acquisition of a clinical site in Tucson, Arizona, operated by PsyPharma, it will be able to provide Phase II-IV trial services across a wide range of sleep and related psychiatric disorders.

PsyPharma specialises in Phase II-IV trials of sleep, psychiatry and neurology disorders, with operations in both the US and China.

Insomnia treatments are the main product category among sleep disorders and represent a multibillion dollar market in their own right, albeit one that is mature and heading for imminent genericisation.

### Quintiles plans Phase I unit in India

[www.outsourcing-pharma.com](http://www.outsourcing-pharma.com)

Contract research organization (CRO) Quintiles has announced a deal with India's Apollo Hospitals Group that will see the two firms collaborate in opening a Phase I clinical trials unit.

The move will allow Quintiles to bolster its presence in the fast-growing Indian clinical research market, which is expected to more than double in size by 2012, according to research published earlier this month by research firm RNCOS.

The new unit is due to open in early 2010 on Apollo's hospital campus in Hyderabad, and will start with a capacity of approximately 50 beds, which will increase to 100 beds if demand develops as predicted.

## RESEARCH BREAKTHROUGHS

### First green light for stem cell clinical trials

[www.outsourcing-pharma.com](http://www.outsourcing-pharma.com)

The US FDA has given the go-ahead to the first clinical trials of a stem cell-based therapy in a major boost to the development of the technology.

Geron Corp has been cleared start trials of GRNOPC1 in patients with acute spinal cord injury - the first time anywhere in the world that an embryonic stem cell therapy has been cleared for testing in humans.

The treatment uses stem cells to regrow the damaged spinal cord cells and - it is hoped - restore function in people with spinal injuries.

This early round of testing will focus on safety, although the study is also designed to measure some measures of efficacy such as improved neuromuscular control or the return of sensation below the site of the injury.

### Cell-building Discovery Could Reduce Need For Some Animal Research

[www.sciencedaily.com](http://www.sciencedaily.com)

Brown University biomedical engineers can now grow and assemble living microtissues into complex three-dimensional structures in a way that will advance the field of tissue

engineering and may eventually reduce the need for certain kinds of animal research.

The team successfully used clusters of cells grown in a 3-D Petri dish also invented by the group, in order to build microtissues of more complex shapes.

Such a finding has enormous implications for basic cell biology, drug discovery and tissue research.

Because the tissues created in the lab are more like natural tissue, they can be constructed to have complex lace-like patterns similar to a vasculature, the arrangement of blood vessels in the body or in an organ. The size, shape and position of cells within these 3-D structures could be controlled. Added complexity could eventually reduce the need to use animals in certain kinds of research.

The finding also makes an important contribution to the field of tissue engineering and regenerative medicine - this could be a step toward using building blocks to build complex-shaped tissues that might one day be transplanted.

## **Breakthrough to Treat Malaria: Scientists Deactivate Malaria Parasite's Digestive Machinery**

[www.sciencedaily.com](http://www.sciencedaily.com)

A team of Monash University researchers led by Professor James Whisstock has made a major breakthrough in the international fight against malaria, which claims the life of a child across the world every 30 seconds.

The team, based at the Monash University ARC Centre of Excellence in Structural and Functional Microbial Genomics, has been able to deactivate the final stage of the malaria parasite's digestive machinery, effectively starving the parasite of nutrients and disabling its survival mechanism. This process of starvation leads to the death of the parasite.

## **Proton Pump Inhibitors Increase Risk of Heart Attacks for Patients on Common Cardiac Drug, Study Shows**

[www.sciencedaily.com](http://www.sciencedaily.com)

Patients taking the common cardiac drug clopidogrel following a heart attack are at a significantly higher risk of a recurrence if they are also taking widely used acid-lowering medications called proton pump inhibitors,

a new study has found.

The study, conducted over 6 years in thousands of heart attack patients aged 66 years and older, found a significantly increased risk of readmission for heart attacks if patients were taking one of several proton pump inhibitors, including omeprazole, lansoprazole, or rabeprazole. The investigators found no such association with the proton pump inhibitor pantoprazole or with other acid-lowering medications called H2 receptor antagonists.

Depending on the exposure to these drugs following a heart attack 5% to 15% of early readmissions for myocardial infarction among patients taking clopidogrel could be the result of this drug interaction. These findings highlight a widely unappreciated, extremely common and completely avoidable drug interaction in a population of patient at very high risk of reinfarction.

Indiscriminate treatment with a proton pump inhibitor could result in thousands of additional cases of recurrent myocardial infarction each year, all of which could be avoided simply by selectively prescribing pantoprazole in patients receiving clopidogrel who require treatment with a proton pump inhibitor.

## **Targeted Nanospheres Find, Penetrate, Then Fuel Burning Of Melanoma**

[www.sciencedaily.com](http://www.sciencedaily.com)

Hollow gold nanospheres equipped with a targeting peptide find melanoma cells, penetrate them deeply, and then cook the tumor when bathed with near-infrared light, a research team led by scientists at The University of Texas M. D. Anderson Cancer Center reported. When heated with lasers, the actively targeted hollow gold nanospheres did eight times more damage to melanoma tumors in mice than did the same nanospheres that gathered less directly in the tumors.

Lab and mouse model experiments demonstrated the first in vivo active targeting of gold nanostructures to tumors in conjunction with photothermal ablation - a minimally invasive treatment that uses heat generated through absorption of light to destroy target tissue. Tumors are burned with near-infrared light, which penetrates deeper into tissue than visible or ultraviolet light.

## **Green Tea Blocks Benefits of Cancer Drug**

[www.sciencedaily.com](http://www.sciencedaily.com)

Contrary to popular assumptions about the health benefits of green tea, researchers at

the University of Southern California (USC) have found that the widely used supplement renders a cancer drug used to treat multiple myeloma and mantle cell lymphoma completely ineffective in treating cancer.

The study, which found that a component of green tea extract (GTE) called EGCG destroys any anticancer activity of the drug Velcade in tumor-bearing mice.

Using preclinical models and tumor-bearing mice, the researchers found that the unusually effective blockage of Velcade's therapeutic activity was based on the chemical interaction between molecules. The EGCG molecule and the Velcade molecule were able to form chemical bonds, meaning that the Velcade molecule could no longer bind to its intended target inside the tumor cells.

The most immediate conclusion from our study is the strong advice that patients undergoing cancer therapy with Velcade must avoid green tea, and in particular all of its concentrated products that are freely available from health food stores.

## **Surgical Implants Coated With One of 'Nature's Antibiotics' Could Prevent Infection**

[www.sciencedaily.com](http://www.sciencedaily.com)

Researchers at the University of British Columbia have discovered a mimic of one of "nature's antibiotics" that can be used to coat medical devices to prevent infection and rejection.

Nature's antibiotics are short natural peptides that are produced by all complex organisms including humans and animals, for protection against microbial infections. These peptides can be found in cells and tissues, on the skin and mucosal surfaces and in fluids like blood, sweat and tears.

These cationic peptides are currently being developed as soluble antibiotics for administration to patients to combat infection. The special feature of these peptides is that they are active when attached to surfaces. When bacteria come into contact with these peptides, the bacteria loses its integrity and destroys itself.

## **Leprosy Medicine Holds Promise as Therapy for Autoimmune Diseases**

[www.sciencedaily.com](http://www.sciencedaily.com)

A century-old drug that failed in its original intent to treat tuberculosis but has worked

well as an antileprosy medicine now holds new promise as a potential therapy for multiple sclerosis and other autoimmune diseases. Clofazimine interferes with a molecular pathway important in orchestrating the human body's immune response.

Clofazimine's molecular target is a protein "pore" called ion channel Kv1.3, which plays an essential role in the complicated signaling process.

Clofazimine blocks the calcium influx into the immune cells; without enough calcium getting inside a cell, the signaling pathway that turns on the immune response is short-circuited. Clofazimine tamps down the presence of free calcium in immune cells by disrupting a potassium channel. The combined effect is to shut down a signaling pathway involved in autoimmune disease.

## Data Mining Promises To Dig Up New Drugs

www.sciencedaily.com

A robot scientist that can make informed guesses about how effective different chemical compounds will be at fighting different diseases could revolutionize the pharmaceutical industry by developing more effective treatments more cheaply and quickly than current methods.

The robot, known as Eve, uses advanced artificial intelligence combined with innovative data mining and knowledge discovery techniques to analyze the results of pharmacological experiments it conducts itself.

By relating the chemical structure of different compounds to their pharmacological activity,

Eve is able to learn which chemical compounds should be tested next, bringing a degree of predictability to drug screening procedures that, until now, have tended to be a bit hit and miss.

Eve will learn to pick out the chemical compounds that are likely to be most effective against a certain target by analysing data from past experiments and comparing chemical structures to their pharmacological properties; Eve could minimise the need for random testing of chemical compounds..

The robot conducts the QSAR testing in assays itself, analyses the results and stores the data for future use. Over the course of numerous experiments, Eve learns which chemical structures are likely to be effective in specific assays. So, instead of choosing compounds to test at random, it can pick ones that are more likely to be effective.

## Forthcoming Events

### 9<sup>th</sup> International Symposium of Controlled Release Society - Indian Chapter

Date : **25<sup>th</sup> - 26<sup>th</sup> February, 09**  
 Venue : ITC Maratha, Andheri (East), Mumbai  
 Contact: Prof. H. L. Bhalla - scitech@bom.5.vsnl.net.in  
 Prof. (Mrs.) K. K. Singh -  
 crsindianchapter@rediffmail.com

### Pharmaceutical Leadership Summit

Date : **3<sup>rd</sup> April, 2009**  
 Vanue : Renaissance Mumbai Hotel and Convention Centre, Mumbai  
 Organized by : Akshay Patra Foundation

### Workshop on 'Dissolution'

Date : **14<sup>th</sup> - 15<sup>th</sup> May, 2009**  
 Organized by : IPA Regulatory Division / AAPS / IPA Karnataka State Branch  
 Contact: Dr. Premnath Shenoy -  
 krpskenoy@yahoo.com  
 Mob No. 9845175011

### Indian Pharmaceutical Association - Students' Congress

Date : **10<sup>th</sup> - 12<sup>th</sup> July, 2009**  
 Venue : DM Acharya College of Pharmacy, Bangalore  
 Organized by : Indian Pharmaceutical Association - Students' Forum  
 Contact Person / details: ipasf@ipapharma.org

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