

## US FDA clears "first-ever" 24 hr liquid SR drug

FDA approval for a 24-hour liquid sustained-release formulation could significantly improve tailored dosing, according to US developer Tris Pharma.

The two newly approved products, a liquid and a tablet formulation of the alpha-2 adrenergic agonist Clonidine, both employ Tris' sustained-release (SR) OralXR+ particle technology to deliver their contents over a 24 hour period.

Tris' OralXR+ platform uses particles coated in an insoluble, taste-masked, water-based polymer that is compatible with a variety of dosage forms, ranging from tablets and capsules to liquid suspensions and film strips.

Clonidine has traditionally been prescribed for hypertension, however it has a variety of other uses ranging from the treatment of narcotic withdrawal and migraine to attention-deficit hyperactivity disorder (ADHD).

## DRUG APPROVALS

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

### Zyprexa Relprevv (olanzapine) for Extended Release Injectable Suspension

Company: Lilly

Treatment for: Schizophrenia

Zyprexa Relprevv (olanzapine) is a long-acting atypical antipsychotic for intramuscular injection indicated for the treatment of schizophrenia.

### Wilate (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) Injection

Company: Octapharma USA

Treatment for: von Willebrand's Disease

Wilate is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease (VWD).

### Kalbitor (ecallanide)

Company: Dyax Corp.

Treatment for: Hereditary Angioedema

Serious allergic reactions may occur, usually within 1 hour after receiving Kalbitor. Some of these include chest tightness, reddening

of the face, itching, hives, runny nose, wheezing.

## REGULATORY UPDATES

### Health ministry bans obesity drug rimonabant following reports of side effects

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

After almost 10 months since the Drugs Technical Advisory Board (DTAB) recommended its prohibition following reports of various side effects, the Union health ministry has banned manufacturing, marketing and imports of the anti-obesity drug rimonabant in the country.

The drug, once considered as an effective weight losing medication, is found to create psychiatric side effects including suicidal tendencies in those who consume it and has been banned in several developed countries. The ban on a product under Section 10-A is imposed in India for the first time after almost 11 years. In 1998, the government had prohibited imports of two anti obesity drugs - fenfluramine and dexfenfluramine - which was the last time when government imposed the Section 10-A before ban of rimonabant.

### Sanofi recalls sub-potent H1N1 vaccine batch in US

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

Sanofi Pasteur has recalled four lots of its pediatric H1N1 vaccine in the US that were found to have fallen below potency limits despite being in spec at the time of manufacture.

The Center for Disease Control and Prevention (CDC) said that the voluntary recall, which affects some 800,000 doses, is not related to any safety concerns and stressed that the vaccine is still expected to elicit a protective immune response.

Despite considerable public demand when the World Health Organisation (WHO) declared the H1N1 pandemic in June, anecdotal reports suggest that influenza vaccine uptake has been lower than expected.

## RESEARCH

### New Clues Emerge for Understanding Morphine Addiction

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

Scientists are adding additional brush strokes to the revolutionary new image now

emerging for star-shaped cells called astrocytes in the brain and spinal cord. Their report suggests a key role for astrocytes in morphine's ability to relieve pain and cause addiction.

Astrocytes- the most abundant cells in the brain- are viewed as supporting actors in the drama of brain activity. Scientists thought astrocytes simply propped up neurons, nerve cells that transmit signals, and kept them in proper position.

The scientists added morphine to a group of astrocytes in cell culture for several days. They found that the morphine-exposed cells showed increased levels of nine proteins that appear to play a role in maintaining the normal function of nerve cells.

These proteins, after additional detailed study of their function, may serve as a potential marker of drug addiction, or may be the targets for potential therapy.

### Birth control pill for men? Scientists find a hormonal on-and-off switch for male fertility

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

Scientists have found how and where androgenic hormones work in the testes to control normal sperm production and male fertility. This opens a promising avenue for the development of "the pill" for men. This could one day give men similar type of control

Shri S. L. Nasa has been elected as President of 62<sup>nd</sup> Indian Pharmaceutical Congress, 2010 to be held in Manipal from 17<sup>th</sup> to 19<sup>th</sup> December, 2010 at Manipal University, Manipal, Karnataka.



Shri S. L. Nasa

over their fertility that women have had since the 1960s. The discovery also offers hope to those who cannot have children because of low sperm counts.

To make this discovery, the scientists performed studies in two groups of mice. The first group of mice was normal, but the second group of mice was missing a gene from the peritubular myoid cells in the testis. This gene that was missing codes for the androgen hormone receptor, and when missing, sperm production was significantly decreased when compared to the normal group. The result was infertility.

## **MERGERS AND CONTRACTS**

### **NYK bags Ranbaxy UK distribution contract**

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

NYK Logistics will be responsible for all the distribution of all the products that Ranbaxy Laboratories, the non-branded arm of Japanese pharmaceutical firm DaiChii-Sankyo, sells in the UK under a new contract announced earlier this week.

The pharmaceutical logistics and supply chain services group, which operates out of a 175,000 sq. feet temperature-controlled facility in Northampton, will receive all batches of Ranbaxy's generic drug products shipped to the country.

### **Teva extends Codexis biocatalyst deal**

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

Teva will continue to use Codexis' biocatalysis technology for key processing steps in the production of four generic drugs under a revised agreement announced last week.

The firms have worked on the project since January last year with Codexis using its proprietary MolecularBreeding technology to develop custom "super enzymes" to accelerate Teva's production processes.

Teva and Codexis' first research collaboration was signed in late 2004, with the Israeli generics giant licensing exclusive rights to commercialise the process in return for providing research funding.

### **Merck & Co to buy Avecia Biologics**

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

US drug major Merck & Co will buy into the UK's contract biologics manufacturing sector with the acquisition of Tees Valley-based Avecia Biologics.

Merck, which will also acquire Avecia's existing manufacturing contracts, said it will speak with the UK firm's customers about ongoing requirements after the deal is concluded next year.

Like many Big Pharma firms facing the loss of patents on top selling drugs, Merck has been ramping up its biologics capacity, beginning last December with the launch of its BioVentures unit, which will make both branded and generic biotech drugs.

Avecia's US contract oligonucleotides production business, based in Milford, Massachusetts, is part of the Merck acquisition.

### **Institut Pasteur Korea Enters Into Agreement with Novartis Institute for Tropical Diseases for Tuberculosis Drug Discovery**

[www.ip-korea.org](http://www.ip-korea.org)

Institut Pasteur Korea (IPK) and Novartis Institute for Tropical Diseases (NITD) Singapore, have entered into a Services Frame Agreement for the identification of safe and effective new therapies for Tuberculosis infected individuals.

This partnership utilizes IPK's proprietary PhenomicScreen™ technological platform with the chemical compound collection of NITD. IPK's expertise in high throughput and high content visual screening approaches accelerates the drug discovery process.

### **After 30 years' gap, IPC prepares National Formulary of India**

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

After a long gap of 30 years, the updated edition of National Formulary of India (NFI) will be available in the country soon as the Indian Pharmacopoeia Commission (IPC) is giving final touches to the NFI and will be published soon. This will be the fourth edition of the NFI and the third edition was published way back in 1979.

The IPC has almost finalized the new edition, which will soon be distributed to the stakeholders like eminent doctors, pharmacists and even nurses in the country for their comments and suggestions before sending the much awaited reference material to final print. The new edition will have around 1000 pages and will be available for the stakeholders at a nominal price which will be fixed at a later stage.

Experts are of the view that the restarting the publication of NFI is important especially in view of the fact that the category and doses of various medicines have not been included in the Indian Pharmacopoeia-2007.

### **India's focus on APIs and generics helped growth in 2009**

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

The Indian pharmaceutical market was worth \$10.8bn (€7.5bn) this year and will more than double in value by 2014 according to a new industry report by Cygnus Business Consulting & Research.

The authors of the "Indian Pharmaceutical Market" report argue that the 13 per cent expansion seen in India over the last 12 months is evidence that the industry was relatively unaffected by the global downturn.

They ascribe this performance to both strong internal demand and the sector's continued focus on active pharmaceutical ingredient (API) and generics production.



## *Appeal for* **IPA Building Fund**

*The President of*  
**Indian Pharmaceutical Association (IPA)**  
*appeals to all members of*  
**IPA to contribute minimum of**  
**Rs. 1000/-**

towards the proposed IPA building at **Mumbai**.  
Kindly send your contribution through D/D or local cheque in favour of

**"IPA Building Fund"**  
on the following address.

**Executive Secretary,**  
**Indian Pharmaceutical Association**  
C/o. Bombay College of Pharmacy, Kalina, Santacruz (E), Mumbai 400098.

**All donations towards this fund will get tax exemption u/s 80G of Income Tax Act.**