



Greetings!

Wishing everyone a Happy New Year 2018!

As always, the start of this year is special for PharmSol Group!

Let me start this editorial with a quote from Benjamin Franklin "An investment in Knowledge always pays the best interest"

It is 14 years ago, we started our journey and since then we have covered a lot of distance. Our Services Portfolios too got expanded over these years and we are able to address the requirements of our clients.

I echo the vision of our Managing Director, Mr. Sunil Doshi i.e. PharmSol being a service provider believes in "Our people are the source and the secret of our success".

The domain in which our space lies is "Knowledge sharing". Therefore, it is essential that we earn/enjoy the respect of our clients by ensuring that we provide them high quality and value-added services, and to position us as a preferred Solution Provider / Problem-Solvers.

Following the above, all our SBUs like Compliance Services, Third Part Audits, Regulatory Services, EU GMP / Authority Inspection Services besides Product Development have taken new trajectory of growth and sustenance. In this new year too, let us proceed with those laid foundation & principles of PharmSol and position us in to new altitude of growth through each of your efforts.

I encourage & Welcome you all to take the time to share your knowledge through our magazine "Pharm Breeze" as part of knowledge sharing!

Once again wishing Good luck and Prosperous year ahead filled with all good things in Abundance to all of us!!

Happy Reading!

S. Lakshmi Narasimhan

Director – Operations, PharmSol Group

"Our people are the source and the secret of our success"

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SCIENCE & NEWS CORNER

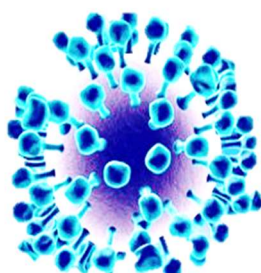
Vegetables



Curd



Can they influence Influenza-A virus?



Lactic acid bacteria can protect against Influenza A virus

Fermented vegetables and dairy products contain a variety of lactic acid bacteria, which have a number of health benefits in addition to being used as probiotics. Studies have found some lactic acid bacteria strains provide partial protection against bacterial infectious diseases, such as *Streptococcus pneumoniae*, as well as cold and influenza viruses.

Read more about this on www.worldpharmanews.com

Nanoparticles

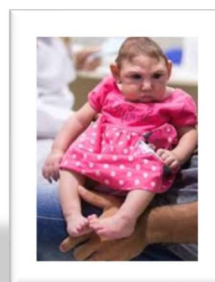
Nanoparticles are particles between 1 and 100 nanometers (nm) in size. The surface area of the nanoparticles is larger than fine particles.



1 kg of particles of 1 mm³ has the same surface area as 1 mg of particles of 1 nm³

Due to its surface area activity, the physical properties of nanoparticles are significantly different than that of the particles of the molecule. For example, the nanoparticle of Gold melt at much lower temperature such as ~300°C for 2.5 nm size, whilst the Gold Slabs melt at 1064°C.

Semi-solid and soft nanoparticles are also available. A prototype nanoparticle of semi-solid nature is the liposome. Various types of liposome nanoparticles are currently used clinically as delivery systems for anticancer drugs and vaccines.



ZIKA Virus

Zika Virus, first isolated in 1947 in Uganda has received its name as it was isolated from ZIIKA forest of Uganda. There is no specific medication for this but medications are given based on the symptoms. The reason why it is important is, it can transmit from a pregnant mother to its infant during pregnancy and may result a child as in in the picture.

Zika remains a research and public health challenge.

Zika virus has become established in more than 80 countries, infected millions of people, and left many babies with birth defects (collectively called congenital Zika syndrome). Zika Syndrome is a "profound medical tragedy" and societal challenge that will require decades of financial, medical and social support.

Read more about this on www.worldpharmanews.com

Nanoparticles as a solution against antibiotic resistance?

Antibiotic resistance can be combated through nanoparticles Boon to patients with Mucoviscidosis: Novel drug delivery (Antibiotics Nanoparticles Inhalational dosage form in the size range of 1-5 micrometers) may increase life expectancy of people suffering with Mucoviscidosis.

Read more about this on www.worldpharmanews.com

SCIENCE & NEWS CORNER



Leflunomide is a drug which inhibits the synthesis of DNA and RNA. Hence, leflunomide inhibits the reproduction of rapidly dividing cells, especially lymphocyte. The drug is used for treating Rheumatoid Arthritis. It is to be noted that Melanoma has similar pathological conditions like arthritis but not the same.

Arthritis drug could help treat advanced skin cancer

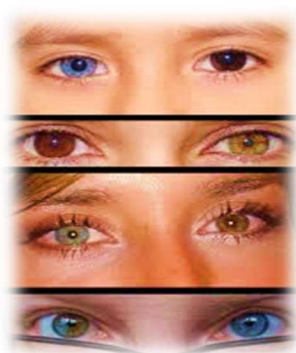
"With melanoma treatments, the main problem has been the development of tumor resistance. One way this is being combatted is through immunotherapy treatments which harness the body's own defenses. leflunomide was acting on the melanoma cells and found that it was able to stop the cells in an early phase of their growth and then force them to kill themselves, a process known as apoptosis.

Read more about this on www.worldpharmanews.com

New software can verify someone's identity by their DNA in minutes

The software is designed to run on the MINION, an instrument the size of a credit card that pulls in strands of DNA through its microscopic pores and reads out sequences of nucleotides, or the DNA letters A, T, C, G. The device has made it possible for researchers to study bacteria and viruses in the field, but its high error-rate and large sequencing gaps have, until now, limited its use on human cells with their billions of nucleotides.

Read more about this on www.worldpharmanews.com



Mutation

In biology, a mutation is the permanent alteration of the nucleotide sequence of the genome. Mutation is classified in four types as Spontaneous mutation, Error-prone replication bypass, Error introduced during DNA repair and Induced mutations.

Distinct human mutations can alter the effect of medicine

Every person has a unique DNA sequence in their genome. Now researchers from the University of Copenhagen and the MRC Laboratory of Molecular Biology in Cambridge have tried to quantify what these differences in the genome mean in the context of the genes targeted by drugs.

Read more about this on www.worldpharmanews.com

USFDA WARNING LETTER

An FDA warning letter is a formal communication from the United States Food and Drug Administration on account of a significant GMP violation which has a serious impact on the health of Humans. This section deals with the warning letters that were issued in this month of coverage.

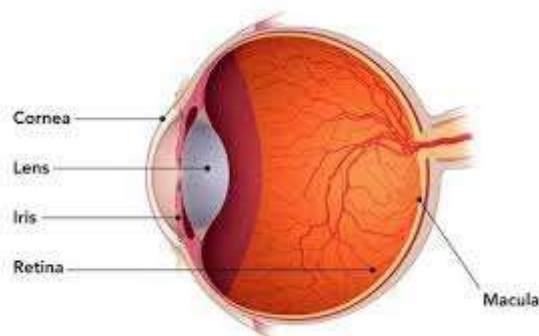
FDA issued warning letter to Aphena Pharma Solutions on fenofibrate and Montelukast sodium as FDA review revealed that the listings for these products include inaccurate information.

FDA issued warning letter to Seindni Co. Ltd. This warning letter summarizes significant violations of (CGMP) regulations for finished pharmaceuticals.

NEW/DRUG APPROVALS

Spark Therapeutics, Philadelphia, are authorized to manufacture Voretigene neparvovec-rzyl, which is indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Read more about this on
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm>



'Dystrophy' means a condition that a person is born with, 'retinal' means relating to the retina - the light sensitive film at the back of the eye. Retinal pigment epithelium-specific 65 kDa protein (RPE65), also known as retinoid isomerohydrolase, is an enzyme of the vertebrate visual cycle that is encoded in humans by the RPE65 gene.

Ferrer International S.A. received FDA approval for XEPI with the Active Pharmaceutical Ingredient OZENOXACIN (Topical/Cream) of a strength of 1% to treat impetigo.

Read more about this on
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=208945>

Impetigo is a medical condition of formation of pustules and yellow crusty sores due to bacterial infection and it is contagious.



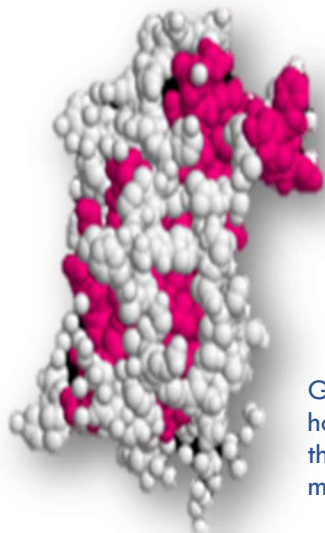
The U.S. Food and Drug Administration today approved GIAPREZA (ANGIOTENSIN II) injection for intravenous infusion to increase blood pressure in adults with septic or other distributive shock.

Read more about this on
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm590249.htm>

"Shock, the inability to maintain blood flow to vital tissues, can result in organ failure and death," said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research. "There is a need for treatment options for critically ill hypotensive patients who do not adequately respond to available therapies."



NEW/DRUG APPROVALS



AETERNA ZENTARIS GMBH received FDA approval for **MACRILEN** with Active Pharmaceutical Ingredient **MACIMORELIN ACETATE** for the diagnosis of growth hormone deficiency in adults.

MACRILEN is available as granules in a pouch. The granules are dissolved in water by a healthcare professional and given by mouth only once in preparation for a blood test that can help detect growth hormone deficiency. The amount given depends on the patient's weight.

Read more about this on <https://www.fda.gov/Drugs/InformationOnDrugs/ucm590519.htm>

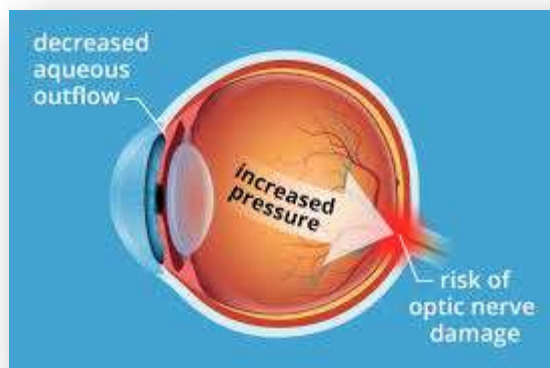
Growth Hormone Deficiency (GHD) is a medical condition due to not enough growth hormone (GH). Generally, the most noticeable symptom is a short height. In newborns there may be low blood sugar or a small penis. In adults there may be decreased muscle mass, high cholesterol levels, or poor bone density.

Aerie Pharmaceuticals INC received FDA approval for **RHOPRESSA**

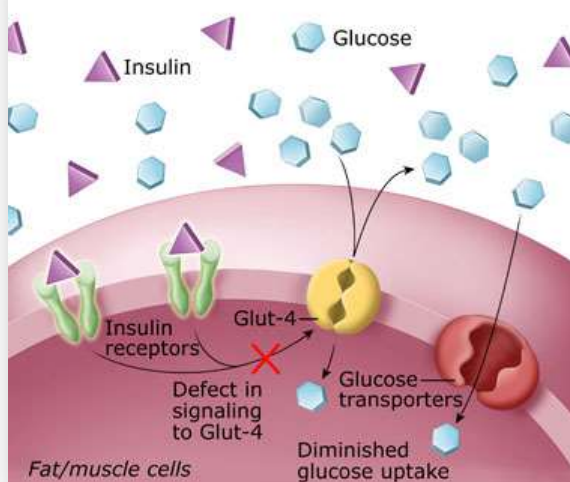
RHOPRESSA is a drug with Active Pharmaceutical Ingredient **NETARSUDIL** for reducing elevated intraocular pressure, when the pressure inside the eye is too high.

RHOPRESSA lowers the intraocular pressure.

Read more about this on <https://www.fda.gov/Drugs/InformationOnDrugs/ucm591430.htm>



Type 2 Diabetes: Insulin Resistance



MERCK SHARP DOHME received FDA approval for **STEGLATRO**

Ertugliflozin (active ingredient), 5mg/15mg Tablet received novel drug approval by FDA to improve glycemic control in adults with type 2 diabetes Mellitus.

Read more about this on <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?ev>

Diabetes mellitus type 2 (also known as type 2 diabetes) is a long-term metabolic disorder that is characterized by high blood sugar, insulin resistance, and relative lack of insulin. Common symptoms include increased thirst, frequent urination, and unexplained weight loss.



HEADLINES FROM THE EU

Modified-release paracetamol-containing products to be suspended from EU market

The CMDh has endorsed by majority a European Medicines Agency recommendation to suspend marketing of modified- or prolonged-release products containing paracetamol (designed to release paracetamol slowly over a longer period than the usual immediate-release products). The recommendation was made by the Agency's experts in medicines safety, the Pharmacovigilance Risk Assessment Committee (PRAC).

New medicine to treat perianal fistulas in patients with Crohn's disease

Alofisel is the tenth advanced therapy recommended for marketing authorisation

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for a new advanced therapy medicinal product (ATMP) for the treatment of complex perianal fistulas in patients with Crohn's disease. Alofisel is the tenth ATMP that has received a positive opinion from the Agency's Committee for Medicinal Products for Human Use (CHMP).

First paediatric medicine to treat rare hormonal disorder

CHMP gives positive opinion to Alkindi for paediatric-use marketing authorisation

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting a paediatric-use marketing authorisation (PUMA) for Alkindi (hydrocortisone) for the treatment of primary adrenal insufficiency, a rare hormonal disorder, in infants, children and adolescents.

First guidance on monoclonal antibodies for use in animals

Guidance supports development of novel veterinary therapies

The European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) has approved the first ever guidance at European Union (EU) level for monoclonal antibody therapies for veterinary use. The guidance was prepared by the CVMP's Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) in the form of a question-and-answer document.

New medicine for rare bone disease

Crysvita, a medicine for the treatment of X-linked hypophosphatemia, recommended for conditional approval

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended granting a conditional marketing authorisation in the European Union for Crysvita (burosumab), a medicine for the treatment of X-linked hypophosphatemia (XLH) with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons.

Read more about this on

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/12/news_detail_00287.jsp&mid=WC0b01ac058004d5c1

RECALLS, MARKET WITHDRAWALS, & SAFETY ALERTS

AUROMEDICS PHARMA LLC issues voluntary nationwide recall of Levofloxacin in 5% Dextrose 250mg/50mL due to presence of visible Particulate Matter tentatively identified as Mold

The affected Linezolid Injection lot being recalled is CLZ160007, EXP. August 2018. No adverse reactions reported from the market.

Read more about this on <https://www.fda.gov/Safety/Recalls/ucm590446.htm>

PHARMEDIUM SERVICES, LLC Issues Voluntary Nationwide Recall of Certain Lots of Compounded Sterile Products due to Lack of Sterility Assurance

The recall is being issued because PharMEDium conducted a retrospective review of all commercially distributed product lots compounded in the Memphis location currently within their labeled expiration date in response to an FDA request.

Read more about this on <https://www.fda.gov/Safety/Recalls/ucm590446.htm>

NEWLY ADDED GUIDANCE DOCUMENTS

Status	Newly Added Guidance Document	Subject
Draft Guidance	Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry	Compliance
	Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Draft Guidance for Industry	Generics/User fees
	Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry	Pharmaceutical Quality/CMC
	Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease; Guidance for Industry	Clinical Pharmacology
	Refuse to File: NDA and BLA Submissions to CDER Guidance for Industry	Procedural
	Gluten in Drug Products and Associated Labeling Recommendations; Draft Guidance for Industry	Labeling
	Pediatric Rare Diseases--A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry	Rare Diseases
Final Guidance	Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs	Labeling
	Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling-Final	Advertising

GRANNY THERAPY/TREATMENT



Nausea: Mix honey with ginger and lemon to counteract nausea.

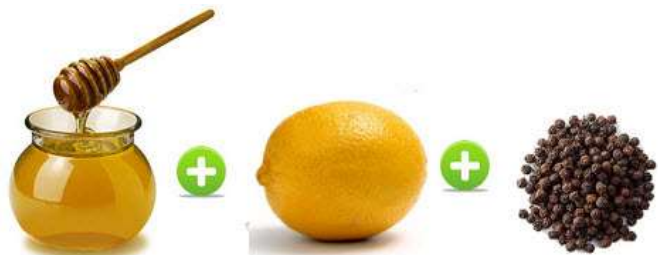


Burn wounds: Applying Aloe Vera to burn wounds accelerate the healing process.



Exercise is a top prescription for Mild cognitive treatment

A mixture of Honey, Lemon and Pepper before food is practiced for 2 to 3 weeks for detoxification and to burn fat.



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