

# Aurous Speak

The Quarterly Newsletter from the Corporate of Aurous HealthCare - *CRO...*  
Mar 2016 Vol. 03 Ed. 03



**DRUG BAN!**

Here's how

**AUROUS**

can

**HELP**

**YOU!**



## From the Desk of MD...

Colleagues and Friends!

Stop and think before you pop that pill!

*I have always been an ardent advocate of "research-ed product" especially medicines that's have undergone stringent testing including independent third party assessments for efficacy and safety.*

Then comes the **big ban slap from CDSCO on over 300 medicines** that were used very commonly in most households!!

Pharma companies have sought a stay on the order, however, the fact that government brought such a ban in place, makes us pause and think!

The most effective way of an amicable resolution in the situation is conducting independent third party clinical studies to prove the safety and efficacy of these fixed dose combination drugs.

Some of the banned drugged are however approved by USFDA itself. Considering that viewpoint of the Government of India, the need of the hour is the most cost-efficient, quality driven clinical studies conducting in the domestic market to assess the safety of the FDC drugs in Indian Population.

I am confident that newer reforms that come with this fiscal year would put the Indian HealthCare and Pharma Research Industry on the Global Map!

Stay hydrated this summer and when you receive this newsletter, give me call or come visit us. Lets sit down ,talk about your product and give it the scientific research credibility the government expects!

Happy New Fiscal Year!!

With best regards,

Dr. VT.Sriraam MBBS MD (Pharmacology)

Managing Director | Medical Director

Aurous HealthCare CRO



*Dr. VT. Sriraam MBBS MD (Pharmacology) is the founder - director of Aurous HealthCare - CRO.*

*An alumni of Stanley Medical College, he was honored as "The Best Doctor" by the Ministry of Health, Maldives at the age of 23.*

*Gaining rich and varied experience at top CRO, Dr. VT. Sriraam founded Aurous HealthCare in 2008. An astute medical entrepreneur, his sharp business sense combined with his rich knowledge and experience in the field of clinical research has pushed Aurous HealthCare from strength to strength.*

*Dr.Sriraam has been recognized with NATIONAL AWARD - "Indian Leadership Award for Healthcare Excellence", for his contributions in the field of medical research*

*A man with strengths so varied and unique, Dr.VT.Sriraam is the epitome of the entrepreneurial combination of business brains and clinical-research creatives.*

## FDCs BANNED in INDIA and they are 344 in Number!

The Health Ministry has banned 344 FIXED DOSE COMBINATION Drugs, leading to an immediate suspension of the manufacturing and sale of some popular medicines in India.

Fixed Dose Combination drugs are when a pharmaceutical combines two or more active drugs in a fixed ratio into a single dosage.

The degree of safety and FDC drugs effects on humans has been long under question- a report by The Hindu says that there are millions of such unapproved formulae in the Indian markets that are unsafe, dangerous and even lethal.

According to the report, it was made mandatory for FDCs to get an approval from the Central Drugs Standard Control Organization) since 1961. However, there's still a huge proportion of unapproved FDC drugs sold over the counter in the country.

The combination is not approved for sale in major pharmaceutical markets, including the United States, United Kingdom, Germany, France and Japan.

After the ban, the company was forced to immediately stop the manufacture and sale of its powerful antibiotic.

The Ministry while banning over 300 drug combinations said that the pose a 'risk' to humans and there are safer alternatives available in the market. The Department said that it had the best of scientists on board to study the effect of these drugs. " We have tried to bring objectivity to the issue by roping in the best of scientists to study the effects" , the Ministry said.

The order hasn't come out of the blue. The government says that the companies were first issued show cause notices and even given a chance to present their case, but some companies hadn't even bothered to respond to the notice.

*The latest information is that the pharma companies have sought a stay order from Delhi HC on the ban. Resolution to be passed soon.*

Source: DNAIndia.com



*Inside...*

List of banned FDC .....	Page 4
AURO Siddha.....	Page 4
Clinical Trials is MUST for Ayurveda...	Page 5
CR Infrastructure - A Perspective.....	Page 6
AURO Quiz.....	Page 6
Stay Hydrated.....	Page 7



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NOW!!**

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### LIST OF COMMONLY USED MEDICINES BANNED IN INDIA...

Below is a list of some of the commonly used FDC banned by CDSCO last month...

- Ascoril C (Cough Syrup)
- Corex , Corex DX (Cough Syrup)
- Zincolid (Cold medicine)
- Ambrolite ST (Cold, phelgm)
- Mucinex DM (For phlegm)
- TUSQ (Throat lozenges)
- Glimitab (Diabetes Mellitus)
- Triexer, Trimetaday (Diabetes Mellitus)
- Otocin (Ear Drops)
- Migran, Migracare, Vasopil (For migraines)
- Dolorin (headache, pain etc)

- Zimnic AZ (Antibiotic)
- Phensedyl, Tixylix and Tossex (Cough Syrup)
- Grillinctus, Grillinctus BM (Cough Syrup)
- Gluconorm PG (Diabetes Mellitus)
- Vicks Action 500 (cold, nose block, headache)
- Crocin Cold and Flu (Cold) Sources: CDSCO



**Let's  
talk  
Clinical  
Studies**

### AURO Siddha...

Nilavembu...

Scientific name: *Andrographis paniculata*

Sanskrit: Kalamegha; Bengali: Kalmegh

Hindi : Kirayat Kannada: Nilabevu ; Malayalam: Kiriyaathth

Tamil: Nilavembu; Telugu: Nelavemaa

Siddha Properties and Action:

*Dengue & Chinkangunya Treatment: Widely regarded and distributed by State Government - Tamil Nadu as treatment for dengue and chikangunya fever and joint pain.*

*Antipyretic, Anti-inflammatory, Analgesic*

*Detoxification: Detoxes blood, liver, spleen for pathogenic endotoxins.*

*Relief from cold: Known to protect and treat common cold.*

*Arthritis: Known to give relief to arthritic pain and inflammation*

*Immunity Booster: Concoction of Nilavembu during monsoon is said to boost immunity against typical infections and fever.*

Ref : Anbarasu K et al./Asian Pacific Journal of Tropical Medicine (2011)819-823

Natarajan S et al. Evidence based Siddha Medical Management of Dengue . WebmedCentral PUBLIC HEALTH 2012;3(11):WMC003808



## CLINICAL TRIAL MANAGEMENT *for Herbal Products - Herbaceuticals & Medicines, Nutraceuticals, Cosmeceuticals.*

*We specialise in conducting END to END clinical trial projects.*

*We cover the entire project from Conception, Study Design, Medical Writing, Project Management, Regulatory Approval, Conduction Of The Clinical Study, Data Management, Statistical Analysis & Report Preparation!*



## ANIMAL TOXICITY & SAFETY STUDIES *exclusively for Herbal Medicines of AYURVEDA and SIDDHA.*



*Our expertise in handling ANIMAL TOXICITY studies as well as CLINICAL TRIALS, gives YOU the UNIQUE ADVANTAGE of an R&D Partner, who is with you... with your product... from safety testing all the way upto marketing!*

### NEW AYURVEDIC DRUGS TO FACE TOUGH CLINICAL TRIALS...

New ayurvedic drugs will be sold in the market only after they go through rigorous clinical trials, and will soon be notified by the government, said people familiar with the development.

While the Modi government is on a major drive to promote yoga and ayurveda globally as key wellness initiatives, it has also decided to clamp down on mushrooming ayurvedic drugs hitting the market without any proven efficacy. This has prompted the Department of Ayush to enforce a stricter regime by mandating clinical trials for every new ayurvedic drug. While the move could open up bigger export markets for ayurveda, it has already raised an alarm in the industry. At present, manufacturers require a licence from state authorities before new drugs are marketed, but there's no need for clinical trials, leading to ambiguity in the regulatory system. The Indian ayurvedic drug market is about Rs 8000 to 9000 crores, which is much less than the Rs 120,000-crore allopathic market.

"With ayurvedic drugs, the problem is that the regulatory structure is very weak. While there are many classical formulation drugs that derive from ancient texts that are listed in the Drugs Act, there are several other patented and propriety drugs that may completely pass through without any safety or efficacy tests. We are now going to ensure that every new drug undergoes a clinical trial, and only based on the results, will the state authorities give a licence to such drugs. We will notify the mandatory clinical trials within the next three months," a senior official from the Department of Ayush confirmed to ET. Starting April, the department will also begin a major drive to check spurious ayurvedic drugs with random sample testing across the country.

Source: Economic Times

### AURO Byte..

CTRI- Clinical Trials Registry of India

[www.ctri.nic.in](http://www.ctri.nic.in)

The CTRI is hosted by ICMR (Indian Council of Medical Research) and is a free and online public record

system for registration of clinical trials being conducted in India. It was launched in July 2007. As of 2009, registration of clinical trials in CTRI has been made mandatory by DCGI - CDSCO. The mission of CTRI is to have all clinical trials conducted in India registered prospectively ie before the enrolment of the first participant. CTRI is also part of World Health Organisation's International Clinical Trial Registry Platform (ICTRP), So all trials registered with CTRI are also registered with WHO.

*Aurous HealthCare is the pioneer CRO to have all its Clinical Trials registered and approved by ICMR CTRI, before conducting the study!*



CLINICAL TRIALS REGISTRY - INDIA  
NATIONAL INSTITUTE OF MEDICAL STATISTICS  
(INDIAN COUNCIL OF MEDICAL RESEARCH)

## INFRASTRUCTURE FOR CLINICAL RESEARCH - A GLOBAL PERSPECTIVE...

The last century has seen tremendous improvements in human health. From the eradication of smallpox to the improvements in maternal and neonatal health, there is much to be happy about.

This has translated to an improvement in average life expectancy; in India for example, the life expectancy in 1915 was 24 years and recent estimates put it at 66 years and these gains are largely driven by the major advances in clinical research.

India today represents a sixth of the global population and therefore a substantial proportion of the global health problems. Many of these are challenges faced elsewhere in the world but there are also issues that are unique to India and the solutions to these problems can come from India alone. Take for instance cervical cancer. In 2012 alone, 266,000 women worldwide died from cervical cancer. The overwhelming majority (close to 90%) of these women were from less developed nations.

A key first step in building a clinical research infrastructure would include the identification and training of *motivated medical*

*personnel with interest and aptitude in clinical research*. Unfortunately, in practice, only a few (if any) address questions of clinical relevance and only a handful are published in peer-reviewed medical journals. This is at the heart of the crisis facing the clinical research infrastructure in India.

The guiding principles must be to address problems that are unique or critical to India (or low-resource settings in general), identifying potential interventions that might be feasible and providing adequate resources to complete the research efforts. We must resolve to fund at least a few large clinical studies every year that address critical healthcare issues in India.

Yet another issue is the regulatory challenges to conducting clinical trials in India. The ethics of clinical trials and possible exploitation of clinical trial participants has been in the news recently on such studies; and concern and criticism on the conduct of clinical trials in India: The Supreme Court and the Government of India have both appropriately taken notice of these issues and instituted measures to address them.

There are many examples of outstanding clinical research programs that are conducting ethical high-quality research in resource constrained settings and addressing important health-care challenges. We must encourage and provide funding for multi-institutional academic cooperative groups that have institutional mechanisms in place to conduct clinical trials that are relevant and ethical in a relatively short period of time.

Clinical research is undoubtedly expensive and resource-intensive, but with some effort it is possible to fund the next generation of high-quality studies. The funding can come from government agencies like the ICMR, non-profit organisations as well as philanthropic support. The recently established Wellcome Trust-Department of Biotechnology (DBT) India Alliance clinical and public health research fellowship is a good example for identifying and funding promising clinical research efforts in India. It is critical for us to continue providing consistent and incremental funding for clinical research efforts (as it is for funding all research activities in the country).

Source: Spoken by Dr. Sham Mailankody, Oncologist and Hematologist At New York.

## AURO Quiz...Clinical Research

- Which is the regulatory body in India monitoring Clinical Trials?
  - FDA
  - CDSCO
  - NHLM
  - TGA
- What is the name of the Indian Clinical Trial Registry?
  - ICTRP
  - DCGI
  - CTRI
  - NIMS
- What is the name of the International Body that provides guidelines for clinical research?
  - ICH
  - ICMR
  - USFDA
  - WHO
- Name the ethical guideline from World Medical Association for clinical trials.
  - Declaration of Helsinki
  - ICH - E3
  - ICH - E6
  - CDSCO - GSR

Next Edition: How well do you understand  
Clinical Research - Part II

Answers on Page 4

## Universal Ethics Committee: The Ethics Committee Division of Aurous HealthCare - CRO...

Universal Ethics Committee (UEC), is a unit of Aurous HealthCare (CRO) that is registered with CDSCO-DCGI holding registration number [ECR/125/Indt/TN/2013](#) & OHRP (Office of Human Rights Protection, United States) - IRB00008683. UEC has been serving the Clinical Research fraternity since 2012 by providing guidance for conduct and ethical clearance for clinical trial projects. Equipped with a GCP and Schedule Y compliant Expert member team, UEC contributes to the conduct of justified human (clinical) trials. We also review and approve Academic and PMS studies...

Contact: [universalethicscommittee@gmail.com](mailto:universalethicscommittee@gmail.com) or via +91-9840909155



**STAY HYDRATED THIS SUMMER WITH ANCIENT AYURVEDIC DRINK - BUTTERMILK...**

Morru in South India, is a common drink in most Indian households. It is roughly called in English as buttermilk. It is the Indian drink for healthy summers and was previously found in every home. There are many health benefits of traditional buttermilk, which will not only let you have a healthy summer season but keep you active and away from summer ailments as well.

Recipe for Traditional Buttermilk:

1 cup Yoghurt / Curd ; 3 cups Water

1/2 teaspoon Cumin Powder ; 2 Green Chillies

1 inch piece of Ginger ; 1 tablespoon Coriander Leaves

Salt to Taste

For Seasoning: 1 teaspoon Oil ; 1 teaspoon Mustard Seeds

Few Curry Leaves



Method of Preparation:

Take curd (yoghurt), water and salt and using a whisk mix it well. Add chopped ginger, green chillies, coriander leaves and cumin powder and mix well.

Heat oil in a pan, add mustard seeds and when the mustard seeds starts to sputter, add hing and curry leaves and fry for 10 seconds and remove from flame and add the seasoned ingredients to the buttermilk and mix well.

Serve the yummy and scrumptious buttermilk as such or serve chilled.

The following are some of the benefits of this traditional drink.

**Buttermilk Keeps the Body Hydrated**

*Buttermilk is a tasty combination of water, curd, essential spices and salt. It is packed with beneficial electrolytes. The salt and water works to keep our body hydrated. It is an excellent drink for summer when we need to fight dehydration.*

**Buttermilk Cuts Down Fats**

*If you feel bloated or simply have eaten too much then drink a little bit of buttermilk. The ginger, pepper and other spices in chaas help to improve the digestion and make you feel less uncomfortable. Apart from that buttermilk is very effective in washing down the fat, oil or ghee that normally coats inner walls of your food pipe and stomach making you feel instantaneously lighter.*

**Buttermilk is High in Calcium**

*Buttermilk is a rich source of calcium. A cup serving of buttermilk will satisfy 28% of your calcium requirements. Calcium is a nutrient that promotes stronger, denser bones. It reduces the risk of bone disease including osteoporosis. Calcium also aids in muscle contraction and supports cell communication.*

**Buttermilk Reduces Blood Pressure**

*Buttermilk is rich in bio-active protein which has antiviral, anticancer and cholesterol lowering properties. Having buttermilk on a regular basis helps in lowering and controlling blood pressure. It works as a natural remedy to reduce high blood pressure.*

**Buttermilk Reduces Cholesterol**

*Buttermilk has several special components which help in reducing cholesterol levels. Consuming a glass of buttermilk everyday helps in reducing cholesterol levels and controls it naturally.*

**Buttermilk Helps with Acidity**

*A powerful tool to fight acidity, buttermilk has essential spices like pepper and ginger that help to beat the burning sensation you feel during a short period of acidity. Moreover the buttermilk cools the stomach and reduces the irritation in the stomach lining due to acid reflux, giving you relief from the discomfort.*

**Buttermilk Has Beneficial Bacteria**

*Buttermilk is teeming with live beneficial bacteria that keep the digestive tract healthy. Probiotics re-balance the flora of the gastrointestinal tract, reducing the risk of bad bacteria overgrowth. Beneficial bacteria also keep the gut healthy, cutting the risk of cancer, diarrhea, and gastrointestinal diseases.*

Source: [www.indiavine.org](http://www.indiavine.org)



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THE PIONEER CONTRACT RESEARCH ORGANISATION (CRO) WITH FOCUS ON CLINICAL RESEARCH

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