ISSUE No. 3

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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EDITORIAL

Dear Readers,

The first two issues of the newsletter were successfully completed in a time bound manner and released to all professional bodies. This is the third issue of the newsletter comprising of various articles and professional information etc., which are useful to our profession. This issue consists of 3 articles. Dr. D. Roy, Dy. Drugs Controller, India, South Zone, Chennai, has continuously taken interest by writing technical articles for the benefit of pharmaceutical manufacturers. In this issue, he has elaborately described the water system to be used for pharmaceutical propose.

Dr. N. Udupa and other professors of Department of Pharmacy, Manipal College of Pharmaceutical Sciences initiated the guidelines for good pharmacy education practices. This article will definitely help various pharmacy teaching institution to improve their capabilities in teaching. An article namely "Antioxidants- Abundant in Nature", which appeared in the Journal of CDRI has been reproduced in this issue, in order to benefit the members of association as well as pharmacy professionals

This issue is also reproducing two important matters namely "Draft Guidelines for registration of Clinical Research Organisations" by Drugs Controller India office. The other article on the subject of "Allowable limit of pesticide residues and microbial count in medicinal plants" appeared in Indian Herbal Pharmacopoeia. We have also included various news items and events useful to our readers.

One of our senior persons, Dr. M. Venkateswarlu, who had recently retired as Drugs Controller General of India suddenly passed away. We pray his soul rest in peace.

I hope the readers may utilise this newsletter for their guidance and also give their valuable suggestions for future issues.

Best regards,
R. Narayanaswamy

ARTICLES

Water for Pharmaceutical Use (WPU)

- Like any starting material, water must conform to Good Manufacturing Practice norms
- It must be "potable" and comply with Guidelines for drinking-water quality

Dr. D. Roy
Central Drugs Standard Control Organization
Ministry of Health, Govt. of India

Water is most widely used substance in a pharmaceutical manufacturing facility. It is used as raw material or starting material in the production, processing and formulation of pharmaceutical product and also used as cleaning agent for machineries & equipment. Water may also be a potent source of contaminant hazards with intended product substances.

Following grades of water quality are required to be used in pharmaceutical processes:
i) Purified Water (PW), ii) Water For Injection (WFI), iii) Softened Water, iv) Water for final rinse, V) Pure or clean steam and vi) Water for cooling Autoclaves.

The grade of water to be used depends on the nature and intended use of the intermediate or finished product and the stage in the manufacturing process at which the water is used, e.g. for oral formulations PW may be used whereas for injectable product preparation, WFI grade is warranted. Water for final rinse must be of the same quality as the water required for pharmaceutical preparation. When steam comes into contact with an injectable product in its final container, or equipment for preparing injectable products, it should conform to the specification for WFI when condensed. Disinfectant solutions for use in aseptic areas shall be prepared in WFI.

Production of PW

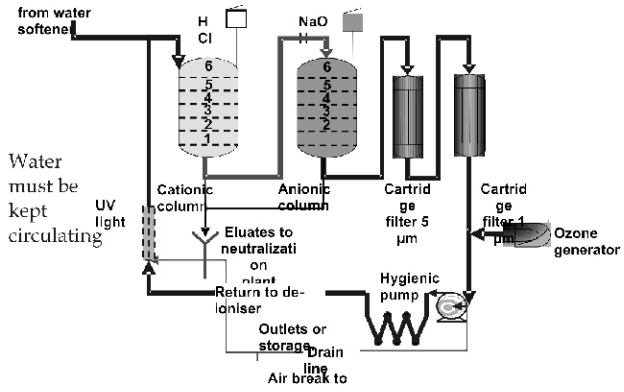
As such no pharmacopoeia or GMP guidelines prescribed the methods for the production of PW. Any appropriate qualified purification technique or sequence of techniques can be used. In general, ion-exchange, ultra-filtration and / or reverse osmosis processes are used. The following should be considered when designing a water purification system:

Feed-water quality
Required water quality specification
Optimum generation size to avoid over-frequents start/stop cycling
Blow-down and dump functions and
Cool-down venting to avoid contamination ingress.

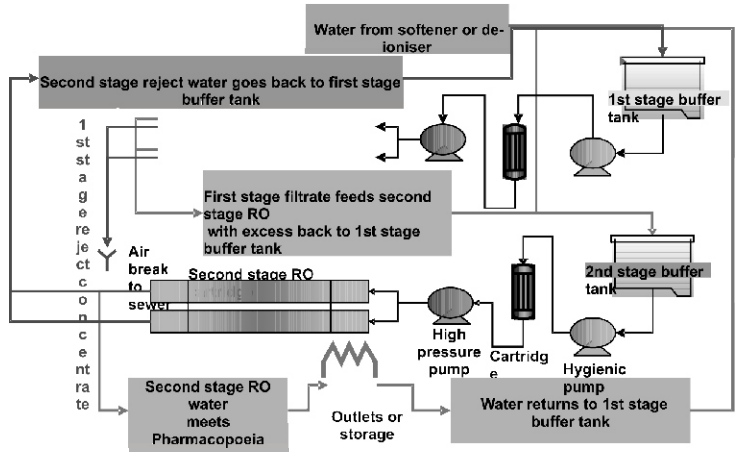
Production of WFI

The pharmacopoeias prescribe the specification of WFI. Revised Schedule M Part-1A prescribes that WFI shall meet microbiological specification of not more than 10 cfu per 100ml and have an endotoxin level of not more than 0.25 EU/ml. Double Distillation process using multicolumn is the preferred technique.

Typical de-ionizer schematic



Typical 2-stage RO schematic



Storage and Distribution of WPU

The storage and distribution system should be considered as a key part of the whole system and should be designed to be fully integrated with the water purification components of the system. The materials that come into contact with WPU, including pipe-work, valves and fittings, seals, diaphragms and instruments, should be selected to satisfy the following objectives.

- Compatibility
- Prevention of leaching
- Corrosion resistance (when stainless steel is used it should be at least grade 316L.)
- Smooth internal finish (the internal finish should have an arithmetical average surface roughness of not greater than 0.8 micro-meter arithmetical mean roughness (Ra).
- Design of flanges or unions (where flanges or unions are used, they should be of a hygienic or sanitary design)
- Documentation. All system components should be fully documented and be supported by original or certified copies of material certificates.
- Materials. Suitable materials that may be considered for sanitary elements of the system include 316 L (low carbon) stainless steel,polypropylene, polyvinylidene difluoride and perfluoroalkoxy.
- Other materials such as unplasticized polyvinylchloride (uPVC) may be used for treatment equipment designed for less pure water such as ion exchangers and softeners.

Requirements for water distribution pipe work

The distribution of PW and WFI should be accomplished using a continuously circulating pipe work loop. Proliferation of contaminants within the storage tank and distribution loop should be controlled.

Circulation pumps

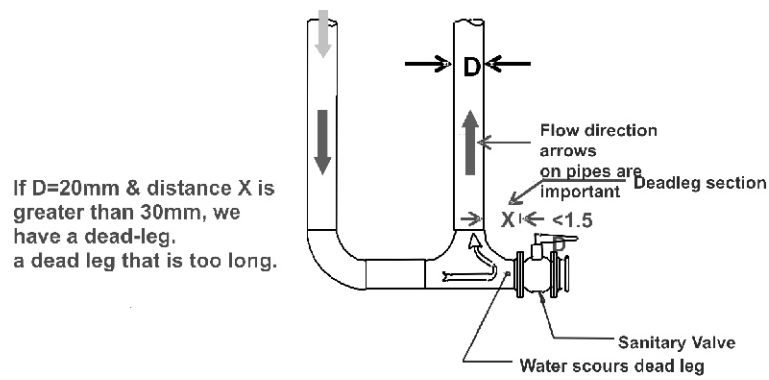
Circulation pumps should be of a sanitary design with appropriate seals that prevent contamination of the system. Where stand-by pumps are provided, they should be configured or managed to avoid dead zones trapped within the system.

Maintenance of continuous turbulent flow circulation within water distribution systems reduces the tendency for formation of bio-films. Dead-legs in the pipe work installation greater than 1.5 times of the branch diameter should be avoided. The flow rate of water is an important parameter and should not be less than twice the capacity of the storage tank per hour (e.g. if the capacity of storage tank is 2KL, flow rate of the water should not be less than 4 KL per hour). The growth of microorganisms can be inhibited by:

Ultra-violet radiation sources in pipe work;
Maintaining the system heated (guidance temperature 70 80 °C);

Circulation pumps

1. Water Quality Manual
2. Water system drawing
3. Validation
4. Sampling procedures, locations and plan
5. Records of testing
6. Sanitation and maintenance
7. Schedules of maintenance
8. Changes made since last review
9. System performance
10. Reliability
11. Quality trends
12. Failure events
13. Investigations
14. Out-of-specifications(OOS) results from monitoring
15. Changes to the installation
16. Updated installation documents
17. Log Books; and
18. Status of the current SOP list



Qualification

WPU system is considered to be one of the critical system which should be qualified. The qualification should follow design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).
A three-phase approach should be in place to satisfy the objective of proving the reliability and robustness of the system over an extended period.

Phase 1. A test period of 24 weeks should be spent for monitoring the system intensively. During this period the system should operate continuously without failure or performance deviation.
Phase 2. A further test period of 24 weeks should be spent for carrying out further intensive monitoring while deploying all the defined SOPs after satisfactory completion of phase 1.
Phase 3. Phase 3 typically runs for 1 year after satisfactory completion of phase 2. Water can be used for manufacturing purposes during this phase.

Continuous system monitoring:

After completion of phase 3 of the qualification programme for the WPU system, a system review should be undertaken. Following this review, a routine monitoring plan should be established based on the results of phase 3. WPU system should be reviewed at regular intervals and the review team should comprise of representatives from Engineering, QA, Operations & Maintenance.

Bibliography

WHO TRS 929
Revised Schedule M
PIC/S; Inspection of Utilities

Shasun launches new drug

Shasun Chemicals & Drugs has launched a recombinant streptokinase, a clot dissolving drug used during heart attacks in collaboration with Council of Scientific and Industrial Research (CSIR). The drug would be marketed by two other Indian companies Lupin and Alembic. Shasun expects to capture 15-17% of the Rs. 80 crore market segment in the first year. The drug will be priced at Rs. 2,200-2,400 per injection for retail market which is comparable with its competitions. But the Chennai-based company believes that as it uses a recombinant (genetic engineering) technology for its drug., it has higher efficacy compared to its competitors that developed similar injection with natural streptokinase.

Source: *The Economic Times, 11th July, 2009*

Antioxidants Abundant In Nature

Wamiq F. Rahman
Documentation and Library Services Division, CDRI, Lucknow

Introduction

We are not actually rusting but our cells are oxidizing the same action as rust, which slowly breaks down our bodies. This is caused by unstable molecules known as free radicals that wreak havoc on the integrity and performance of our body cells. The human body derives its energy from the utilisation of nutrients and oxygen as fuel. It also utilises oxygen to help the immune system, destroys foreign substances and combats diseases. The by-product of this and other metabolic processes can lead to the development of molecular agents that react with body issues in processes can lead o the development of molecular agents that react with body tissues in a process called oxidation. While this process is a natural consequence of the energy generation system, its by-product called "free radicals" can damage healthy cells of the body. Free radicals also cause oxidation in the blood.

Free Radicals

A free radical is an unstable molecule that steals an electron from a stable molecule in order to satisfy its needs for repair. In doing so, this free radical destabilises the stable molecule and creates another free radical in a vicious chain of cellular destruction. A single free radical can cause damage to millions in our body, preventing our body from functioning properly. This molecular destruction is continually occurring in our body.

Although free radicals are a result of breathing but these free radicals attack us from many different sources everyday. Some of which are: Alcohol, Tobacco, Drugs, smoked and barbecued food, harmful chemicals and Pesticides, food additives, dietary lipids, strenuous exercise, chronic disease, Sun-bathing and pollutants in the air we breathe. They assault our cells, large enzyme complexes, vitamin C and DNA.

Once oxidation occurs, disease can result. Free radicals are believed to be one of the causes of over sixty health problems. These problems include cancer, diabetes, Emphysema, Arthritis, Neurological disorders Such as Alzemer's Disease and Parkinson's diseases. Various cardiovascular problems including Stroke, Atherosclerosis and heart attack, various Autoimmune diseases such as Multiple Sclerosis, Crohn's Disease and Lupus, various eye diseases including Macular Degeneration and cataracts. Various skin problems such as Hair Loss, Rough Skin and Wrinkles and also the problem of ageing. The major source of ageing is the production of free radicals and with the age, the amount of free radicals we produce increases. Scientists have determined that very large amounts of free radicals accumulated in our body, may significantly shorten our life span.

Antioxidants

Studies over the last twenty years have shown that free radical fighters found in a certain group of nutrients, namely Antioxidants, can protect against a great many free radical initiated diseases. Antioxidants extinguish free radicals. Antioxidants help:

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- Destroy the free radicals that damage cells.
- Promote the growth of healthy cells.
- Protect cells against premature, abnormal ageing.
- Help fight age-related macular degeneration.
- Provide excellent support for the body's immune system, making it an effective disease preventative.

The term Antioxidant originally was used to refer specifically to a chemical that prevented the consumption of oxygen. In the late 19th and early 20th century, extensive study was devoted to the uses of antioxidants in important industrial processes, such as the prevention of metal corrosion, the vulcanisation of rubber and the polymerisation of fuels in the fouling of internal combustion engines.

Early research on the role of antioxidants in biology focused in their use in preventing the oxidation of unsaturated fats, which is the cause of rancidity. Antioxidant activity could be measured simply by placing the fat in a closed container with oxygen and measuring the rate of oxygen consumption. However, it was the identification of vitamin A, C and E as antioxidants that revolutionised the field and led to the realisation of the importance of antioxidants in biochemistry of living organism.

The possible mechanisms of action of antioxidants were first explored when it was recognised that a substance with anti-oxidative activity is likely to be one that is itself readily oxidised. Research into how Vitamin E prevents the process of lipid peroxidation led to the identification of antioxidants as reducing agents that prevent oxidative reactions, often by scavenging reactive oxygen species before they can damage cells.

Natural Antioxidants

Antioxidants have been around since life began. Basically they are natural substances found in plants and animals that protect the fats, proteins and nucleic acids from premature ageing and destruction from ultraviolet light found in sunlight, cosmic radiation, chemicals and internally generated free radicals etc. Certain species such as Ginger and Turmeric were used as natural "Food Preservatives" long before the word "Antioxidant" was coined. Basically certain spices, herbs and nutrients, called antioxidants, help prevent damage to fats, proteins and nucleic acids in plant and animal tissues by neutralising destruction by active molecules called "Free Radicals"

A paradox in metabolism is that while the vast majority of complex life requires oxygen for its existence, oxygen is a highly reactive molecule that damages living organisms by producing reactive oxygen species. Consequently, organisms contain a complex network of antioxidant metabolites and enzymes that work together to prevent oxidative damage to cellular components such as DNA, Proteins and Lipids. In general, antioxidants either prevent these reactive species from being formed or remove them before they can damage vital components of the cell. Antioxidants work in several ways. First, they may reduce the energy of the free radical form forming in the first place. And finally antioxidants interrupt the oxidising chain reaction to minimize the damage caused by free radicals.

Antioxidants are classifieds into two broad divisions depending on whether they are soluble in water (Hydrophilic) or in lipids (Hydrophobic). In general, water soluble antioxidants react with oxidants in the cell cytoplasm and the blood plasma, while lipid-soluble antioxidants protect cell membranes from lipid peroxidation. These compounds may be syntheised in the body or obtained from the diet. The different antioxidants are present at a wide range of concentrations in body fluids and tissues, with some such as Glutathione or Ubiquinone mostly present within cells, while others such as Uric Acid are more evenly distributed throughout the body.

The relative importance and interactions between these different antioxidants is a complex area, with the various metabolites and enzyme systems having synergistic and interdependent effects on one another on the proper function of other members of the antioxidant system. The amount of protection

Provided by anyone antioxidant therefore depends on its concentration, its reactivity towards the particular reactive oxygen species being considered and the status of the antioxidants with which it interacts.

Our bodies produce several antioxidant including Superoxide Dismutase (SOD), Glutathione Peroxidase and Catalase, that destroy many types of harmful free radicals. Supplements of these enzymes are available for oral administration. However supplementing with the building blocks the body uses to make Superoxide Dismutase, Catalse and Glutathione Peroxidase may prove to be more effective. These building block nutrients include the minerals Manganese, Zinc and copper for SOD and Selenium for Glutathione Peroxidase.

In addition to enzymes, many vitamins and minerals such as Vitamin C, Vitamin E, Bets-carotene, Lutein, Lycopene, Vitamin B2, Coenzyme Q10 and Cystiene (an Amino acid) act as natural antioxidants. Antioxidant work together to get the job done. For example, Beta-carotene will not be able to reduce the risk of cancer without Vitamin C, Vitamin E and Selenium. The primary antioxidants are phytochemicals, which help our bodies repair themselves and offer us stronger immune systems. The primary antioxidants are:

Carotenoids Lycopene, Lutein and Beta-carotene etc.

- Vitamin C
- Vitamin E
- Alpha lipoic acid
- Selenium
- Anthocyanins
-

Although free radicals are a result of breathing but these free radicals attack us from many different sources everyday. Some of which are: Alcohol, Tobacco, Drugs, smoked and barbecued food, harmful chemicals and Pesticides, food additives, dietary lipids, strenuous exercise, chronic disease, Sun-bathing and pollutants in the air we breathe. They assault our cells, large enzyme complexes, vitamin C and DNA.

Once oxidation occurs, disease can result. Free radicals are believed to be one of the causes of over sixty health problems. These problems include cancer, diabetes, Emphysema, Arthritis, Neurological disorders Such as Alzemer's Disease and Parkinson's diseases. Various cardiovascular problems including Stroke, Atherosclerosis and heart attack, various Autoimmune diseases such as Multiple Sclerosis, Crohn's Disease and Lupus, various eye diseases including Macular Degeneration and cataracts. Various skin problems such as Hair Loss, Rough Skin and Wrinkles and also the problem of ageing. The major source of ageing is the production of free radicals and with the age, the amount of free radicals we produce increases. Scientists have determined that very large amounts of free radicals accumulated in our body, may significantly shorten our life span.

All the above primary antioxidants are freely available in our daily diet, if we take proper food. Nature provides us the tools to fight with the enemies of our body system. Consumption of a wide variety of antioxidant enzymes, vitamins and minerals in natural form is recommended as the best way to provide the body with the most complete protection against free radical damage. Natural antioxidants are most abundant in fruits and Vegetables as well as in other foods including Grains, Nuts, some red meats, poultry and fish.

Carotenoids are a class of natural pigments that is widespread and it was demonstrated that they occur in all the three domains of life, i.e. in the Eubacteria, the Archea and in the Eucarya. A rich source for carotenoids is the Algae and more than hundred carotenoids have been isolated and characterised from these organisms. For human beings the most important sources of carotenoids are plants. The carotenoids are responsible for the beautiful colours of many birds, insects and marine animals. Carotenoids, like Lycopene, Lutein, Beta-carotene, Alpha-carotene, Cryptoxanthin and Zeaxanthin can lower the risk of cancer and heart diseases. These antioxidants can even revert the damage done by certain cancerous cells. It suppresses the formation of bad cholesterol (LDL) in the body. Carotenoids also boost immunity in the body.

Lycopene is a potent antioxidant. Consumption of foods rich in Lycopene reduces the risk of prostate cancer and cardiovascular disorders. Lycopene is not produced in the body, so we can only obtain it by eating foods rich in Lycopene. Lycopene is most commonly found in Tomatoes, watermelon, Papaya, Guava, Apricots, Pink Grapefruit and Oranges. It is estimated that the maximum dietary intake of Lycopene comes from tomatoes and tomato based products.

Lutein is the primary antioxidant in preventing blindness, cataracts and other disorders of the eyes, particularly as we age, Lutein is more readily absorbed when cooked and served with some fat, butter or oil, Lutein can be found in dark leafy green vegetables, richly colored fruits such as collards, Bell Peppers, Carrots, Corn, Leeks, Kale, Mangoes, Melon, Honeydew, Oranges, Peas, Romaine, Hard Squash, Spinach, Sweet Potatoes, Tomatoes and yolk of eggs.

Beta-carotene converts into vitamin A (Retinol) by our body system. It prevents cancer and heart disease and boosts immune system of the body. Beta-carotene can be found in many foods that are orange in color including, sweet potatoes, Cantaloupe, Apricots, Squash, Pumpkin, Mangoes, Spinach, Kale, Broccoli, Peaches, Tomatoes, Whole Grain, Spirulina, Tea, Coffee, Egg Yolk, Milk, Butter and Liver.

Vitamin C and Vitmain E work together to protect each other from oxidation. They reduce the risk of some age-related diseases. We need a regular supply of these vitamins through our daily diet.

Vitamin C is water soluble. It reduces the risk of age related diseases and prevents cancer. It is found in Indian Gooseberry, Citrus Fruits, Green Peppers, Cabbage, Spinach, Broccoli, Kale, Cantaloupes, Kiwi, Strawberries and Spirulina. It can also be found in Cereals, Beef, Poultry and Fish products.

Vitamin E, also known as Alpha-tocopherol is fat soluble. It reduces the risk of age-related diseases, keeps bad cholesterol from sticking to artery walls (Therefore reduces the risk of heart attack), protects cells from potentially cancer-causing free radials. It is founding Sunflower oil, Corn oil, Soyabean oil, Olive oil, Fish oil, Peanut Butter, Spirulina, Wheat Germ, Mango, Walnut, Almonds, Hazelnut, Fish, Whole Grains, Apricots, Avocados, Sweet Potatoes and Broccoli.

Alpha-lipoic acid also known as Thioctic acid is a known antioxidant and is widely used in prevention of various diseases. Its main function is to increase production of glutathione, which helps dissolve toxic substances in the liver. Scientists discovered the importance of alpha-lipoic acid in early fifties and recognized it as an antioxidant in 1988. The body needs alpha-lipoic acid to produce energy. It plays a crucial role in the energy producing structures in cells. It was quickly discovered to be a very

important cofactor in the Krebs cycle (Citric acid cycle), the body's main process for converting carbohydrates into energy. The body actually makes enough Alpha-lipoic acid for this basic function. Alpha-lipoic acid is a versatile antioxidant and experts consider it a “universal”, “metabolic” and “ideal” antioxidant. It neutralises free radicals in both the fatty and watery regions of cells.

Alphalipoic acid is perhaps the most active biological antioxidant discovered so far. It is one of the broadest acting antioxidants, neutralising a variety of free radicals. One of the most beneficial effects of Alpha-lipoic acid is its ability to regenerate other essential antioxidants, such as vitamin C, Vitamin E, coenzyme Q 10 and glutathione. The body routinely converts some lpha-lipoic acid to dehydro-lipoic acid, which appears to be an evermore powerful antioxidant. Both forms of lipoic acids quench peroxynitrite radicals, an especially dangerous type consisting of both oxygen and nitrogen.

Research into the beneficial effects of alpha-lipoic acid is receiving increasing attention and there is already substantial experimental and clinical evidences to the effect that alphalipoic acid may be useful in the prevention and treatment of such diverse conditions as diabetes, heart disease, HIV infection, neurogenerative diseases, cancer, liver problems, heavy metal poisoning and radiation Damage. Alpha-lipoic acids can be found in foods such as Mutton, Liver, Spinach, Broccoli, Potatoes and Yeast. Alpha-lipoic acid is readily synthesized in the body and is well absorbed from the diet through the stomach and intestine. It is also easily absorbed in to the blood stream and can cross the blood brain barrier.

Selenium is a trace mineral, not technically an antioxidant in its own right. However, it is an important component of most antioxidant enzymes. Plant foods like rice and wheat are the most common dietary sources of selenium. The concentration of selenium in soil, which, varies by region, determines the amount of selenium in the crop grown in that soil. Consequently, animals that eat trains or plants grown in selenium-rich soil have higher levels of selenium in their bodies. It reduces the risk of death from cancer, lowers risk of skin cancer and reduces the chance of arthritis and rheumatoid arthritis. Brazil Nuts top the list of all selenium-rich foods. It is also found in Walnut, Spirulina, Beef, Mutton and fish specially Tuna Fish.

Anthocyanins are water soluble, versatile and plentiful flavonoid pigments found in red/purplish fruits and vegetables. Within the plants, they serve as key antioxidants and pigments contributing to the coloration of flowers, vegetables, cereals grains and fruits. These plant pigments are more than coloring agents for fruit juices, wine and other beverages. They protect the plant tissues from photo inhibition or high light stress. During the process of photosynthesis, a tremendous number of free radicals are produced. The plants require a high concentration of antioxidants to protect against cellular damage. Plant pigments, primarily Carotenoids and Flavonoids are largely responsible for this protection. Research has shown that ingestion of these compounds by human beings result in similar protection. In negative circumstances, plants increase the formation of anthocyanins to protect them. They also contain an array of health-promoting benefits. Anthocyanins show anti-cancer properties, normalize circulatory disorders, prevent diabetes and ulcers. They show an anti-inflammatory effect and improve eye sight. Anthocyanins boost the immune system, cut down the excess cholesterol and slow down the ageing process. The main source of anthocyanins are Cherry, Purple Cabbage, Beets, Blue Berries, Raspberries, Purple Grapes, plums, Blueberries, Apple, Pineapple, Kiwi, Blue Berries, Goose berries, Black Berries, Elder Berries, Black Carrot, Chokeberries, Red wine, Straw Berries and Black Currant.

Herbal Antioxidant Since early Neanderthal man, plants have been used for healing purposes. Even as modes of medicine changed throughout the centuries, plants continued to be the mainstay of country medicine a methods and ideas on plant healing were passed down from family to family, and within communities. Thus tribes, clans, villages, towns, sometimes entire countries, tended to have similar styles in healing. Most of these plant remedies were based on local discoveries and pass along uses, so it is always interesting to note how many plants are used in exactly the same way in different part of the world.

Even though much of the medical community ignores, perhaps even disdains, plant medicine as too old fashioned, plants are nonetheless the basis for some of the most effective drugs. For several thousand years, the Chinese physicians used the Ma Huang plant in the treatment of respiratory disorders. Later, researchers extracted an alkaloid, Ephedrine, from this plant. This is still used in many different ways, namely for relief of nasal congestion, bronchial coughs and Asthma. Pharmaceutical firms from all over the world continue to comb the more primitive places on earth to explore and define native folk medicine. They bring back various botanical specimens in the hope of discovering plants that can be successfully duplicated. Experimental evidence suggests that free radicals and reactive oxygen species can be involved in a high number of diseases. As plants produce a lot of antioxidants to control the oxidative stress caused by sunbeams and oxygen, they can represent a source of new compounds with proven antioxidants activity. In normal life of a human being, intake of antioxidants routine diet is the main source to fight against the free radicals of the body and it is a continuous process. Selection of food items rich in antioxidants is a very important factor to live a healthy life. In addition to dietary antioxidants, there are a number of herbs which serve as antioxidants. Herbal antioxidants refer to those herbs that help counter the oxidation process by scavenging free radicals before they attack healthy cells. Use of antioxidants has recently got prevalent in modern medicine. Although for centuries together, in the traditional system of medicine all over the world, experts have been using many herbs for this purpose without knowing that those herbs served as antioxidants. The basic concept of treatment in traditional system of medicine is to check the degenerative process of the body and improve its immune system along with the treatment of particular ailment.

Ayurveda, the Indian traditional health care system, is one of the oldest systems in the world. This system provides an approach to prevention and treatment of different diseases by practicing medical procedures and using pharmaceuticals. One of the clinical specialties of Ayurveda is Rasayana. Rasayana is not only a drug therapy but it is a specialised procedure practiced in the form of rejuvenating recipes, dietary regimen and promoting good habits. The purpose of Rasayana treatment is in two folds: prevention of disease and counteraction of ageing process. The meaning of the word Rasayana (Rasa: Extract or essence, Ayana: Going) essentially refers to nutrition and its acquisition, movement, circulation and perfusion in the body tissues. In modern system of medicine, experts have indirectly adopted the principle of treatment from traditional or ayurvedic system of medicine as far as use of antioxidants is concerned. Herbs, serving as antioxidants, are available in every part of the world with different names. India is very rich in flora and fauna. Medicinal plants, in India are found in some region or the other. Thick forests of the country provide a number of medicinal plants. This is the reason why the physicians in olden times concentrated on hills and forests. With rapid awareness of the significance of herbs, today cultivation of medicinal plants is in progress resulting in conservation of many rare herbs and plants. Thousands of herbs are being used by the physicians of Ayurveda for the treatment of various diseases, out of which a few are being used with proven antioxidant activity. The list of Indian medicinal plants which serve as antioxidant is as follows:

S.No.	Genus/(Local Name)	Family	Part	Fraction
1	Allium sativum (Lassun)	Liliaceae	Bulb	Aqueous
2	Aloe vera (Gheekanvar) Syn. A. Barbadensis	Liliaceae	Leaf Pulp	Aqueous
3	Annona muricata (Sharifa)	Annonaceae	Seeds, Leaves	Alcoholic
4	Arthrospira maxima syn. A. plantensis (Spirulina)	Phormidiaceae	Whole Plant	Aqueous
5	Beriberis orthobotrys syn. B. Lyceum (Dharuhaldi)	Berberidaceae	Roots	Aqueous
6	Camellia sinensis(Tea)	Theaceae	Leaves	Aqueous
7	Cinnamomum zeylanicum Syn. C. verum (Dalchini)	Lauraceae	Seeds	Aqueous
8	Curcuma longa Syn. C. Domestica (Haldi)	Zingiberaceae	Rhizomes	Aqueous
9	Emblica Officinalis Syn. Phyllanthus Emblica(Amla)	Euphorbiaceae	Fruits, Leaves Roots, Bark & Flower	Aqueous
10	Eucalyptus globulus (Eucalyptus)	Myrtaceae	Leaves	Aqueous / Alcohol
11	Garcinia mangostana (Mangustan)	Clusiaceae	Fruits	Methanol
12	Gardenia angusta Syn. G. jasminoids (Gandharaj)	Rubiaceae	Bark	Aqueous
13	Ginkgo biloba (Ginkgo)	Ginkgoaceae	Whole Plant	Aqueous
14	Glycine max Syn. G. Soja (Bhat)	Papilonaceae	Seeds	Aqueous
15	Glycyrrhiza glabra (Mulhatti)	Papilonaceae	Roots	Aqueous
16	Gymnocladus dioica (Coffee)	Fabaceae (Formerly Leguminosae)	Seeds	Aqueous
17	Inula helenium (Rasan)	Asteraceae	Roots	Aqueous

S.No.	Genus/(Local Name)	Family	Part	Fraction
18	Melaleuca alternifolia (Kayaputi)	Myrtaceae	Leaves	Aqueous
19	Momordica charantia Syn. M. balsamica (Karela)	Cucurbitaceae	Unripe Fruits and Seeds	Aqueous
20	Origanum majorana (Murwa)	Lamiaceae	Leaves	Aqueous
21	Osbeckia chinensis (Chulasi)	Melastomataceae	Fruits	Aqueous
22	Panax gingseng Syn. Aralia quinquefolia (Indian Ginseng)	Araliaceae	Whole Plant	Aqueous
23	Phaseolus vulgaris(Bakla)	Papilonaceae	Beans	Aqueous
24	Pinus hlepensis(Aleppo Chir)	Pinaceae	Bark	Aqueous/Acidic
25	Polygonumhydropiper(Paku r-mul)	Polygonaceae	Leaves	Aqueous
26	Quercus acutissima Syn. Q. Serrata(Mazuphal)	Fagaceae	Bark	Alcoholic
27	Rheum officinale(Hindi Revandchini)	Polygonaceae	Leaves	Aqueous
28	Rosmarinus officinalis (Rusmari)	Lamiaceae	Whole Plant	Aqueous
29	Rubia cordifolia (Manjith)	Rubiaceae	Roots	Aqueous
30	Salvia officinalis (Salbia sefakhuss)	Lamiaceae	Aerial Part	Aqueous
31	Santalum album(Chandan)	Pedaliaceae	Bark	Aqueous
32	Sesame orientale Syn. S. Indicum(Til)	Pedaliaceae	Seeds	Aqueous
33	Silybum marianum (Gurmur)	Asteraceae	Seeds	Aqueous
34	Stellaria media(Khukwa)	Caryophyllacea	Flowering Plants	Aqueous
35	Swertia chirata Syn. Gentiana chyrayta (Chiratia)	Pedaliaceae	Seeds	Aqueous

S.No.	Genus/(Local Name)	Family	Part	Fraction
36	Tamarindus indica(Imli)	Caesalpiniaceae	Seeds	Ethanolic
37	Terminalia chebula(har)	Combretaceae	Fruits, Leaves	Ether/Phenolic
38	Thymus vulgaris (banajwain)	Lamiaceae	Whole Plant	Aqueous
39	Withania sominfera Syn. Physalis flexuosa (Ashwagandha)	Solanaceae	Roots, Leaves & seeds	Aqueous
40	Zingiber officinale (Adrak, Sonth)	Zingiberaceae	Rhizome	Aqueous/alcoholic

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Good Pharmacy Education Practices: New Era of Pharmacy Edification

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In the desire of building vibrant pharmaceutical sector, Indian government and regulatory authorities have concentrated their efforts for improving the standard of quality pharmacy education. Association of Pharmaceutical Teachers of India is playing major role in this process. It is a healthy sign that pharmacy academicians remain so committed to the profession. Indian education system is widely recognized and appreciated by the world. In the verge of fusion between Indian and western education system, Indian education system retained and proved its essence. This education pattern is equally important in professional education as well.

Indian Pharmaceutical Industry is growing annually at the rate of 13 %. Global Pharmaceutical sector is marching towards the advancement in New Drug Discovery, Nanotechnology, and Novel Drug Delivery. New streams like Nutraceuticals, Cosmeceuticals, Dermaceuticals, and Nutricosmeceuticals are emerging from the basic branches of Pharmaceutical Sciences. Sparkling growth of the Pharmaceutical sector and emergence of new Streams of Pharmaceutical sciences needs highly and specifically skilled professionals. Current Pharmaceutical curriculum is mainly focused and oriented towards industrial needs. There is a need of modifying the curriculum and orienting it towards the specific needs of the industry including research, operations, instrumentations, and management.

Vibrancy of the pharmaceutical sector is dependant on the skills of the professionals which they are getting through education system; it reflects the importance of education system. Athur Chickering and Zelda Gamson, has described seven principles for good practice in education. These seven Principles are nothing but seven strategies for improving the education practices. These Principles are compiled in a study supported by the American Association for Higher Education, the Education Commission of the States, and The Johnson Foundation. Details of implementation strategies of seven principles are discussed as1-

1. Encouraging Student-Faculty Contact

Faculty and student are most important parts of education system. In education system Student-Faculty contact is the most important aspect. Encouraging frequent student-faculty contact and interaction in and out of classes is an important factor in student motivation and involvement. Encouragement and assistance from the faculty help students to deal with learning problems and keep on working. Frequently interacting with the faculty may enhance students' intellectual commitment and encourage them to think about their own values and future career plans. I would also increase their involvement in the learning process which is the ultimate objective of Good Education Practices.

2. Encouraging Cooperation Among Students in the Process of Learning

Good learning, like good work, is collaborative and social, not competitive and isolated. Working with others often increases involvement in learning and helps in understanding the concept easily. Good co-operation among students helps in sharing their own ideas and responding to others' reactions, in this process they can improves their thinking and deepens the understanding. Encouraging Co-operation among students in learning process helps in building their overall personality.

3. Encouraging Active Learning

Learning is not a spectator process; it needs active involvement from the both sides (Faculty and Student). Students do not learn much just sitting in classes listening to teachers, memorizing pre-packaged assignments, and mugging up the answers. In the process of Good Education Practices, practice emphasizes more on active learning process than the mere listening. Good Education Practices encourage learners to participate actively in the discussion on the concept and relate it.

4. Good Practice Gives Prompt Feedback

Good Education Practices given more importance for the prompt and transparent feedback of students as well as faculty members. Transparent feedback helps students as well as faculty about their strengths and weaknesses. Accordingly they can modify their teaching and learning strategies. It is observed that students do not learn much just sitting in classes listening to teachers, memorizing pre-packaged assignments, and spitting out answers. Practice of Good Education believes in getting started, students need help in assessing existing knowledge and competence. In the classroom, students need frequent opportunities to perform and receive guidance for betterment in their performance. Students need to know themselves about what they have learned, how to apply the gathered knowledge, what they still need to know, and how to evaluate themselves.

5. Good Practice Emphasizes Time on Task

Good Education Practices has given due importance for time in the process of education. It is considered that time plus energy equals learning. Time on task has its own importance in the process of education and it should be efficient, effective and more productive. Students as well as faculty members need to learn to manage their time. Students need proper guidance and assistance in effective time management. Allocating realistic amounts of time means effective learning for students and effective teaching for faculty. Under the good Education Practice, institution should define time expectations for students, faculty, administrators, and other professional staff. By doing this they can establish the basis for high performance for all.

6. Good Practice Communicates High Expectations

Good Education Practices emphasize more on Principle of 'High Expectation'. It is considered that high expectations help students to achieve more. As mentioned in some of the management theories high expectations are important for everyone for the poorly prepared, for those unwilling to exert themselves, and for the bright and well motivated because high expectations will derive better results by improving performance of the individual for achieving more. Expecting students to perform well and expecting faculties to contribute more becomes a ladder of success for the education institution.

7. Good Practice Respects Diverse Talents and Ways of Learning

Process of learning is never narrowed. Good Education Practices focuses on diverse learning and teaching techniques. Process of Good Education Practices encourages different learning and teaching techniques such as Problem Based Learning method. Problem Based Learning methodology has been proved as on of the most successful teaching methodology. It involves active participation and co-operation of students. It also fosters the communication skills of students which will help them in improving their overall personality. There are many techniques of teaching, use of advanced technology for teaching is one of them. People bring different talents and styles of learning. Students need the opportunity to show their talents and learn in ways that work for them.

It is observed that, since the Seven Principles of Good Education Practice were created in 1987, new

Communication and information technologies are being used as major resources for teaching and learning in higher education. Prompt, transparent feedback and performance appraisal would definitely help in promoting the quality education practice. As guided by the Good Education Practices, new techniques and technologies should be used in teaching process. Regular training camps for the faculty members should be arranged to update the knowledge and skills of teachers. Academic activities should not confined to teaching and learning process. There should be due importance for research activities as well as overall personality development of faculties and students. Updated pharmacy curriculum is the need of the hour; therefore regulatory authorities should modify their regulations for frequent up gradation of the pharmacy curriculum. Seven principles of Good Education Practice should be implemented in spirit for better practice of education.

Compiled in a study supported by the American Association for Higher Education, the Education Commission of the States, and The Johnson Foundation. Source:

http://www.csus.edu/tltr/assessment/7principles.htm

"Implementing the Seven Principles: Technology as Lever" by Arthur W. Chickering cited at

http://www.tltgroup.org/programs/seven.html

R&D tax benefit cheer spreads to all sectors

Budget 2010 has doled out a substantial tax break for research & development with the finance ministers saying R&D spend in all manufacturing sectors, with the exception of a small negative list, will benefit from tax deduction. A weighted tax deduction of 150% - if R& D spend is Rs. 100, tax able income is reduced by Rs 150-is right now available to companies in a few sectors like pharma.

Sanjaya Kapadia, executive director (direct tax) at Price Waterhouse Coopers said." Earlier, the weighted deduction was applicable to only a few sectors. It is a welcome step to open it to others sectors." Weighted tax deduction benefits companies as it reduced their taxable income and tax liability, the FM has proposed to expand the benefit to all sectors except for those mentioned in the 11th Shedule firms producing alcohol, tobacco, cosmetics, toiletries, dental care products and aerated drinks.

Naveen Aggarwal, ED (direct tax) at KPMG, commented: "The proposals has a much wider coverage and is going to encourage innovation and entrepreneurs. It is going to benefit industries like software, which have captive R&D units in India but were not eligible for tax deduction. It is also going to give a push to the manufacturing sectors that are involved in developing new designs."

Said R Chandrasekaran, President and MD, global delivery, Cognizant:" A substantially higher outlay should increase the R&D throughput and innovation quotient in a material way." The pharma industry is pleased that it has been extended. It had actually made a representation for the tax deduction to be increased to 200%. "The fact that the FM has expanded the scope to include more sectors is a good thing," Mr. Kapadia said.

Source: *Economic Times, 7th July 2009*

Pesticide Residues and Microbial Count in Medicinal Plants

The use of pesticide in agricultural sector has greatly reduced the presence of insect, fungi and moulds in the plants. However, prolonged or excessive usage of pesticides on the crop ultimately toxicates the entire plant material causing several health hazards. Limits for pesticide residue should be established based on the recommendations of the Food and Agriculture Organisation (FAO) and the World Health Organization (WHO) These recommended guidelines for the food and animal feed provide the analytical methodology of pesticide residues[1].

Classification of pesticide

A classification based on the chemical composition and / or structure of the pesticide can be made as follows:

- **Chlorinated hydrocarbons and related pesticides:** Aldrin, benzene hexachloride (BHC) or hexachlorocyclohexane (HCH), chlordane, DDT[2], dieldrin, endrin, heptachlor, methoxychlor, toxaphene (campheclor).
- **Chlorinated phenoxyalconic acid herbicides:** 2,4-D; 2,4,5-T.
- **Organophosphorus pesticides:** Carbophenothion[3], chlorothion, coumaphos[3], demeton, dichlorvos, dimethoate, ethion, fenchlorphos[3], malathion, methyl parathion, parathion.
- **Carbamate pesticides:** Carbaryl[3]
- **Dithiocarbamate fungicides:** Ferbam, maneb, nabam, thiram, zineb, ziram
- **Inorganic pesticides:** Aluminium phosphide calcium arsenate, lead arsenate.
- **Pesticides of plant origin:** Tobacco leaf and nicotine pyrethrum flower, extract and pyrethroids, Derris root and rotenoids.
- **Miscellaneous:** Bromopropylate, chloropicrin, ethylene dibromide, ethylene oxide, methyl bromide.

Methods for the determination of pesticide residues

Chromatography and other procedures are the most successful when determining pesticide residues. Samples are extracted by a standard procedure, impurities are removed by partition and / or adsorption and the presence of moderately-broad spectrum of pesticides is measured in a single determination. However, these techniques are not universally applicable. Some pesticides are carried through the extraction and cleaning-up procedures satisfactorily, others are recovered with a poor yield and some are lost entirely. As a result of limitations in the analytical technique and incomplete knowledge of pesticide interaction with the environment, it is not yet possible to apply an integrated set of methods which will satisfy all situations.

Therefore, it is desirable to test plant materials of unknown history for broad group of compounds rather than testing for individual pesticides.

If the pesticide to which the plant material has been exposed is known or can be identified by suitable means, as well-established method for the determination of that particular residue should be employed.

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1. Joint FAO/WHO Food Standards Programme, CAC/Vol. 13, 2nd Ed.(1986).
2. The International Nonproprietary Name (INN) of this substance is clofenotane.
3. The Internation Nonproprietary Names (INN) of these substances are: carbofenotoin, caumafos, carbaril, fenclofos, respectively.

General aspects on the analytical methodology

1. After collecting the samples these should be tested as quickly as possible before any physical and chemical changes occur. If prolonged storage is envisaged, the samples should preferably be stored in air-tight containers under refrigeration. Alternatively, the material can be extracted and solvent should be removed. The extracts should be stored in a cool place.
2. Light can cause degradation of many pesticides, therefore it is advisable to protect the samples and any extracts or solutions from undue exposure.
3. Solvents and reagents used in the analytical method should be free of substances that may interfere with the reaction, alter the results or that may provoke degradation of the pesticide residue in the sample.
4. The simplest and quickest procedure should be used to separate unwanted material from the sample (Cleanup procedure) in order to save time when many samples have to be tested.
5. The process of concentrating solutions should be made with great care, especially during the evaporation of the last traces of solvent in order to avoid losses of pesticide residues.

Maximum limit of residues for medicinal plant materials

The maximum residue limit (MRL) for medicinal plant materials, including their preparations such as tinctures, extracts, oils. etc. Should be defined within the limits of pesticide residue set by the FAO/WHO Codex. Since medicinal plant materials are usually taken in much smaller quantities than other food products, the MRL can be calculated based on the maximum acceptable daily intake (ADI) of pesticide fro humans and the maximum daily dose (MDD) of the medicinal plant material.

Where the nature of the pesticide to which the plant material has been exposed is unknown, it is necessary to determine only the content of total chlorine and to base the calculation on the MRL of the most toxic chlorine containing pesticide (eg. aldrin or dieldrin).

If the exact nature of the pesticide to which the vegetable drug has been exposed is known, the determination of that particular pesticide residue can be carried out according to well-established procedures1.

Medicinal plant materials normally carry a large number of bacteria and moulds, often of soil origin. While a wide range of bacteria and fungi from the naturally-occuring microflora of herbs, aerobic spore forming bacteria frequently predominate. Current practices of harvesting, handling and production often cause additional contamination and microbial growth. The determination of Escherichia coli and count may indicate production and harvesting practices use. Some of the pathogenic bacteria seen in plant material are E. Coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus.

Depending on the nature of the crude medicinal plant material, grind, dissolve, dilute, suspend or emulsify the material to be examined using a suitable method and eliminate any antimicrobials properties by dilution, neutralization or filtration. WHO[1] has laid detailed procedure for the pretreatment of water soluble material, non fatty materials insoluble in water and for fatty materials. The procedures for detection and quantitative evaluation of some pathogenic bacteria in plant material are also described in the WHO guidelines.

Microbial contamination limits in medicinal plant materials
Different limits are set according to the use of the material and the material itself:

a) Contamination of "crude" plant material intended for further processing (including additional decontamination by any physical or chemical process).

The limits are given for untreated plant harvested under acceptable hygienic conditions (These could possibly indicate problems occurring during handling practices and would need further investigation):

Per gram - maximum 104 Escherichia coli
maximum 105 mould propagules

b) Plant materials that have been pretreated (E.g. Boiling water as used for herbal teas and infusions) or if the material is used for topical dosage forms:

Per gram - maximum 107 aerobic bacteria
maximum 103 saccaromycetes and Hyphomycetes
maximum 102 Ecsherichia coli
maximum 104 other enterobacteria

c) Other plant materials for internal use:

Per gram - maximum 105 aerobic bactria
maximum 103 Saccaromycetes and Hyphomycetes
maximum 101 Escherichia coli
maximum 103 other enterobacteria
no Salmonellae

1. Quality control methods for medicinal plant materials who ISBN 92 4 1545 10 0 (NLM: QV 766) 1998

Source: *Indian Herbal Pharmacopoeia, New Edition 2002*

Registration Of Clinical Research Organisation

The proposed draft rules for Registration of Clinical Research Organisation are being published for the information of all persons likely to be affected thereby for comments, if any. These guidelines have been approved by DTAB for placing it on website for information of the public and comments. Any Person interest in making any objection or suggestion on the proposed draft rules may do so in writing for consideration of the CDSCO within a period of 45 days from the date of its uploading through post to the Drugs Control General (India), CDSCO, FDA Bhavan, Kotla Road, New Delhi 110002.

Proposed Amendments To The Drugs & Cosmetics Rules, 1945 For Registration Of Clinical Research Organisation

Rule 122 DAB. Registration of clinical research organisation for conducting clinical trials.

1) The clinical research organisation contracted in writing by the sponsor to carry out any or all obligations transferred to it by the sponsor, shall perform such functions only, if it is duly registered, under the rules, by the Licensing Authority defined in Clause (b) of Rule 21.
2) An application for registration of clinical research organisation shall be made to the said authority accompanied by the information as required under Schedule Y-1.
3) If the licensing authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules have been complied with and the conditions of registration will be observed, he may grant registration subject to the conditions stated there in.
4) A registration, unless it is sooner suspended or cancelled, shall be valid for a period of five years from the date of issue.
5) If the licensing authority is not satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and the conditions which must be satisfied before the registration can be granted.
6) If the clinical research organisation fails to comply with any of the conditions of registration, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as deemed fit.
7) The clinical research organisation, whose license has been suspended or cancelled by the licensing authority, may within ninety days of the receipt of the copy of the order by him prefer an appeal to the Central Government and the Central Government may after giving an opportunity of being heard, confirm, reverse or modify such order.

Explanation:- For the purpose of this part a clinical research organisation is an individual or a company or an organisation contracted by the sponsor or a part of the company sponsoring clinical trial, that takes the responsibility under a legal contract for the management, documentation, co-ordination and one or more trial related duties or functions assigned to it.

Schedule Y-1 (See Rules 122 DA, 122 DAA, 122 DAB)

Requirements and Guidelines for registration of clinical research organizations

1. Scope

These guidelines cover all organisations, individuals, institutions and companies that takes the responsibility of the initiation or management or coordination of a clinical trial. It does not include clinical trial sites. An individual who both initiates and actually conducts , alone or with other

Associates, a clinical investigation and under whose immediate directions the test article is administered or dispensed or used involving a subject would be exempt. These guidelines are not stand alone guidelines and are not in derogation of any other rules or guidelines applicable to the clinical trials e.g. Schedule Y of the rules, Indian GCP guidelines and Ethical Guidelines for Bio-Medical Research on human subjects by ICMR or any other similar guidelines applicable to the clinical trial.

2. Criteria for Registration

i. The Clinical Research Organisation shall be under the charge of a person who is responsible for the overall activities of the organisation. He shall be thoroughly familiar with the investigational product(s), the protocol, written informed consent forms or other information provided to the subjects, the standard operative procedures by the sponsors, GCP guidelines and other rules applicable to the conduct of clinical trials.

ii. The organisation shall have adequate resources, qualified and trained staff for oversight of clinical trials. The staff members are required to be trained regularly to update their skills

iii. The trial related duties and functions transferred to and assumed by the Clinical Research Organisation shall be specified in writing and properly quantified.

iv. The organisation shall ensure that the trials are adequately monitored and the trial related responsibilities transferred to it, partially or fully, by the sponsor are discharged effectively and efficiently.

v. The organisation shall implement quality assurance and quality control as per standard operative procedures designed for the purpose. Such SOPs shall be well documented.

vi. The organisation should check the accuracy and completeness of the data/documents and other related records and ensure that the investigator(s) have maintained the essential documents required for the conduct of the trial.

vii. The organisation shall ensure that the investigator(s) received all documents and trial related supplies needed to conduct the trial properly.

viii. The organisation shall have education programmes to help its investigators to carry out the research studies as per guidelines applicable to such trials. Training will include protocol adherence, seeking a free and fair informed consent and responding to concerns of research participants during the study.

3. Record Keeping

All records (written documents, electronic, magnetic or optical records, scans, etc.) such as protocols, approvals from the CDSCO & ethics committee, investigator(s) particulars, consent forms, monitor reports, audit certificates, relevant letters, reference ranges, completed and the final reports, shall be maintained. All documentation and communication are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures.

4. Information required for registration

(i) Name and address of the organisation to be registered along with its telephone no., fax no., e-mail address.
(ii) Name and address of the proprietors/partners/directors.
(iii) Status of the organisation as legal entity.
(iv) A brief profile of the specific activities/services undertaken by the organisation including facilities, resources and infrastructure.
(v) An organogram of the organisation including brief CVs of key personal.
(vi) List of SOPs with salient highlights about specific areas to be scrutinised.
(vii) Copy of the contract between the sponsor and the organisation.
(viii) An undertaking to declare that

(a) We shall comply with the conditions imposed on the registration certificate along with the adherence to other guidelines like GCP guidelines and provisions of the Drugs and Cosmetics rules, 1945.
(b) We shall comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules, made thereunder.
(c) We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the premises and to examine the process/procedure and documents in respect of any clinical trial conducted by us for which the registration certificate has been made.

Source: *Internet, www.cdsco.nic.in*

Mandatory registration of clinical trial in ICMR Clinical Registry www.ctri.in reg

Government of India has made compulsory registration of clinical trial in ICMR w.e.f.15th June 2009, which will be applicable for clinical trials initiated after 15th June 2009. Accordingly, while granting permission for clinical applicable for clinical trials, applicants are now being informed that registration of clinical trial in ICMR clinical trial Registry www.ctri.in before its initiation will be mandatory from June 15th 2009.

Source: *Internet, www.cdsco.nic.in*

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health)

NOTIFICATION

New Delhi, the 22nd 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 13th October, 2006 in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i) dated the 13th 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 percent shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration less than or equal to one percent, 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 Standard as 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]

DEBASISH PANDA, Jt. Secretary

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

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

New Delhi, the 22nd 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".

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

Foot Note:- The Drugs and Cosmetics Rules as amended upto 30th June, 2005 have been published in the Government of India publications PDGHS-93 on the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 and last amended vide No. G. S. R. 780 (E), dated 10.11.2008.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

New Delhi, 20th April, 2009

G. S. R.262 (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 for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty five 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 addresses to the Secretary (Health), Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, 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 (Second 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 the rule 122E, in the Explanation for item (i), the following shall be substituted, namely:-
"(i) all vaccines and Recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under rule 21,"

[F. No. X-11014/10/2007-DFQC]
DEBASISH PANDA, Jt. Secretary

Note: The principal rules were published in the Gazette of India vide notification Number F.28-10/45-H (1), dated 21st December, 1945 and last amended vide G. S. R. 116(E), dated 24th February, 2009.

NEWS

The IPA Convention 2009

Theme: Reengineering Pharmacy Profession in India

March 14th and 15th 2009
Venue: Delhi Institute of Pharmaceutical Sciences & Research (DIPSAR), New Delhi.

Indian Pharmaceutical Association (IPA) organized this event at the two-day long thought-provoking event, sought to bring forth many important issues for **"Reengineering the Pharmacy Profession in India"** and to discuss the current trends and issues Indian Pharmacy profession has been facing today and how the Pharmacists can prepare themselves to be influential members as healthcare providers of the country. During the congress, more than 2000 enthusiastic delegates comprising members of academician and Indian Pharmaceutical industry discussed the significant issues related to the industry and the professional fraternity.

His Excellency, Hon'ble Dr. A. R. Kidwai, presently the Governor of Haryana was the Chief Guest. The Health Minister of Delhi Government, Prof. Kiran Walia graced the occasion and Dr. Kamal Midha, President, Federationale Internationale de Pharmaceutique (FIP) was the Guest of Honour. The other dignitaries who adorned the Dias were Prof. S. S. Agrawal, Director of DIPSAR and the Chairman of LOC, Dr. B. Suresh, President, Indian Pharmaceutical Association, Dr. Praful D. Seth, Vice President FIP.

On the inaugural day 5 Symposia were held covering different sections of Pharmacy like - **Community Pharmacy Division:** Trends in Community Pharmacy, **Hospital Pharmacy Division:** Role of Pharmacists in Healthcare in the developing world, **Industrial Pharmacy Division:** Needs of the Industry - Technology, Innovation & Research, **Regulatory Affairs Division:** Regulatory challenges for 21st Century and **Education Division and Students' Forum:** Pharmacy Education Present and Future.

There were also 5 panel discussions **Community Pharmacy Division:** Action Plan for Community Pharmacy Development in India Concrete Steps & Role of Stake Holders, **Hospital Pharmacy Division:** Role of Pharmacists in Healthcare in the developing world, **Industrial Pharmacy Division:** Challenges for the growth of Indian Pharmaceutical Industries, **Regulatory Affairs Division:** Regulatory challenges for 21st Century and **Education Division and Students' Forum:** Pharmacy Education Present and Future.

On the second day, there were three plenary sessions on the topics **Pharmacovigilance by** Prof. S. S. Agrawal, **Molecular Mechanisms of Angiogenesis: Therapeutic Targets for Chronic Heart and Lung Diseases by** Dr. Hari S. Sharma, and **Regulatory Control of Drug Information in India Are we anywhere by** Dr. K. Weerasurya.

The scientific presentations included 10 oral presentations and 179 poster presentations in various divisions. Best poster and oral presentations were awarded.

Overall, there were 70 resource persons (National and international) addressed the delegates during the congress. All the scientific sessions were well attended and were useful for all the professional and student delegates.

Source: *Pharma Times, Vol 41, No. 5, April 2009*

Ranbaxy plans new growth hormone drug

Ranbaxy Laboratories is planning a new growth hormone product to target the emerging global market for new versions of patent-expired biotech drugs, a person familiar with the development said.

The country's largest drug maker is in talks with an unnamed vendor to manufacture a delivery device to inject the drug and the company could be looking at launching its growth hormone in three to five years, the person said on condition of anonymity. A Ranbaxy spokesperson declined to comment.

Human Growth Hormones (HGH) are used to treat growth-related deficiencies in children and adolescents but have also become popular as anti-ageing drugs in the US and Europe. Since the drug is often injected into the patient's body, the quality of the delivery device determines the commercial success of a product.

HGH products are increasingly becoming a lucrative segment of the biosimilar drugs, which are new versions of innovator biopharmaceutical products officially approved following patent expiry.

The market for such drugs is expected to touch $16 billion in the US and Europe by 2011. Large global pharmaceutical players such as Pfizer, Merck Sereno, Eli Lily, Novo Nordisk and Sanoz dominate the HGH market.

The market for HGH biosimilars opened up in 2003 when patents on Eli Lily's growth hormone product Humatrope and Genetech's growth hormone product Nutropin expired. This paved the way for generics players to file for approvals of new versions of these products.

Sandoz's Somatropin is the first HGH biosimilar drug to be approved by European Medical Agency in 2006 and Japan's ministry of health, labour and wealth in June this year.

Since there is not enough data to determine the size of the growth hormone market, 2008 sales of Pfizer's Genotropin at $898 million and Merck Sereno's Saizen at $300 million reveal the potential of the market.

Source: *The Economic Times, 11th July 2009*

Domestic Pharma market to hit 420-billion mark by 2015

Riding high on branded generic wave, the Indian pharmaceutical market is expected to hit the $20-billion mark by 2015 and likely to feature among the world's top 10 pharma markets from its current position of 14th. The domestic pharma market may register a growth of 13% (from around $7billion in 2008 to $20 billion in 2015) as compared to 4% growth of the global pharma market ($650 billion in 2007 to $844 billion in 2015). In terms of absolute growth, India will be next to the growth potential of the US, China and Japan.

Indian market has emerged as a key destination for global pharma companies, thanks to its high growth prospects and conducive regulatory environment. Underlying this fact, the Indian subsidiaries of global pharma companies outperformed their parent companies in terms of sales and profit growth in last three years. On an average, Indian subsidiaries grew by 14% vis-à-vis 5% growth of parent companies in 2008.

According to industry experts, MNC pharma companies are likely to witness a sea change in their strategy and are aggressively scouting for growth options. The MNCs have embarked on a multi-pronged strategy to establish their stronghold in Indian market by introducing patented products, divesting non-core business, going in for acquisitions, strengthening sales and distribution network as well as developing India-centric portfolios. "Strong cash flows and healthy balance sheets, high dividend pay-outs, out performance of the domestic market and strong patent product pipeline make the Indian MNC pharma companies an attractive investment proposition, "Feel experts.

Research firm Emkay Research in its latest report on the pharma industry said that with dwindling growth rates in the developed markets, declining productivity and a potential revenue loss of 14-41% over the next 3-4 years, most of the global companies are renewing their focus on the fast growing emerging markets. Growing and ageing population, changing disease profile coupled with improving socio-economic conditions are the key growth drivers in the emerging markets.

"Companies are increasingly allocating more resources to their Indian subsidiaries, which promise strong growth potential. Have put aside concerns regarding safety of their IP rights and are adopting a more aggressive stance as regards launch process is expected to gain momentum in the days to come", noted the document. Experts are of the view that over the years, Indian subsidiaries of MNC pharma companies have undergone heavy restructuring and divested non-core business, in order to focus on their branded formulation segment. The buyback and de-listing announcements by MNCs strengthen the fact that the parent companies are quite positive on the future growth prospects of their Indian operations.

Moreover, these announcements provide additional upside potential to the stock. Indian MNC pharma companies appears to be largely insulated from the current economic slowdown because of their strong business model and healthy balance sheets, high dividend yield and relatively low risks to earnings, say the experts.

Pointing out that the per capita pharma spend in India significantly lags behind that of other emerging markets, the experts say increased healthcare spending will increase the contribution of the total healthcare market in India to the country's GDP from 5.2% at present to 8.5% over the next ten years. Also, the rise in disposable income has a positive impact on healthcare spend, which has increased from 2.8% in 1995 to 6.2% of disposable income in 2005.

Source: *IDMA Bulletin XL (21) 7th June 2009*

Compulsory Registration of Manufacturers and Wholesalers of Psychotropic Substances

IDMA has received a communication from Smt Jagit Pavadia, Narcotics Commissioner, Central Bureau of Narcotics, Through email (as reproduces below), requesting for the comments/suggestions on the Online registrations of Manufacturers and wholesalers of Psychotropic Substances.

1. Psychotropic substances are substances, natural or synthetic, or any salt or preparation of such substance or materials included in the list of psychotropic substances specified in the schedule to the narcotic drugs and psychotropic substances (NDPS) Act, 1985. The use of Psychotropic substances for medical and scientific purposes should not be unduly restricted. However, the abuse of these substances could result in damage to public health and consequent socio-economic problems.

2. The United Nations (UN) Convention on Psychotropic substances, 1971 (link http:/www.incb.org/pdf/e/conv/convention 1971 en.pdf) has been adopted by the world community to establish an international control system for psychotropic substances. It responds to the diversification and expansion of the spectrum of drugs of abuse and introduces controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other. The said Convention obligates each country to provide such measures as it considers appropriate to regulate manufacture, export, import, distribution and stocking of, trade in and use and possession of psychotropic substances for medical and scientific purposes. It requires the countries to control all duly authorized persons and enterprises carrying on or engaged in the manufacture of, trade (including export and import trade) in or distribution of psychotropic substances.

3. India is a signatory to the UN Convention on Psychotropic Substances, 1971 and is required to comply with the provisions made there under for achieving the goals of the Convention. The Government of India is required to ensure that manufacturers and all other persons authorized to trade in and distribute psychotropic substances keep records showing details of the quantities manufactured, quantity, date, supplier and recipient. The records and information referred above are required to be preserved for atleast two years.

4. The Government of India is required to furnish annual statistical report i.e. Form "P" (link http:// www.incb.org/pdf/e/list/form p e.pdf) to the International Narcotics Control Board (INCB), Vienna. The report shall be prepared in accordance with Form "P" containing the information on quantities manufactured, exported to and imported from each country or region as well as stocks held by manufacturers. The INCB, Vienna has set a deadline for the submission of annual statistical report (Form "P" and this report shall be submitted to the INCB as soon as possible and not later than 30th June of the year to which the statistical data relate.

5. As you are aware, the administrative structure for Drug Control in India is divided between Central Govt. and State Govt. Further, within the central Govt., the control is divided between different Departments/Authorities. The current administrative control structure presents difficulties with regard to sharing of data between the agencies involved and in respect of collection of information to be furnished to the INCB. As a result, the submission of annual statistical reports to the INCB during past years has not been done resulting in inappropriate level of compliance with the said UN Convention. The INCB has also noted that the submission of annual statistical report (Form "P") by India has deteriorated over the last few years. Further, the annual statistical report (Form "P)

Submitted by India over the last few years does not include data on manufacturers of psychotropic substances. The State Drugs Controllers are not able to provide data on manufacture of psychotropic substances to the DCG (I)

6. The INCB may suggest the following actions against a party to ensure the execution of the provisions of the 1971 Convention:

If the INCB has reason to believe that the aims of this Convention are being seriously endangered by reason of the failure of country to carry out the provisions of this Convention, the INCB may ask for country concerned.

After taking action, the INCB, if satisfied that it is necessary to do so, may call upon the government concerned to adopt such remedial measures as shall seem under the circumstances to be necessary for the execution of the provisions of this Convention.

If the INCB finds that the Government concerned has failed to give satisfactory explanations when called upon to do so, or has failed to adopt any remedial measures which it has been called upon, it may recommend to the parties that they stop the export, import, or both, of particular psychotropic substances, form or to the country concerned.

7. The INCB had sent a mission to India in the year 2003 to examine the performance of the drug control measures taken by the Government of India. The INCB Mission has recommended the establishing of clear cut procedure for the collection and exchange of data and for reporting of such data to the INCB, as appropriate.

The INCB has taken up the matter with the relevant authorities of the Government of India for taking remedial measures for improving the collection and compilation of statistical data. A high level team had made a study and recommended that there should be compulsory registration of manufacturers and wholesalers of psychotropic substances in India with the Narcotics Commissioner, Central Bureau of Narcotics, Gwalior to improve the collection and compilation of statistical data

9. The issue has been examined and a decision has been taken to register manufacturers and wholesale distributors for psychotropic substances through web-based On-line system and monitor such manufacturers and wholesale distributors through e-filling of quarterly returns. It has been decided t amend Rule 65 of the NDPS Rules, 1985 providing for compulsory Registration of all manufacturers and wholesalers of psychotropic substances with the Narcotics Commissioner.

10. The computer based system for online registration of the manufacturers and wholesalers of psychotropic substances of e-returns has to be operationalised before promulgation of any new rules under the NDPS Rules, 1985. A System Requirement Study the National Informatics Centre (NIC). The views / comments of the manufacturers and wholesalers of psychotropic substances who would be using the system are essential for incorporation in the SRS to facilitate the trade as well as to fulfill the international obligations.

Attention is invited to an article on "Compulsory Registration of Manufacturers and Wholesaler of psychotropic substances with the Narcotics Commissioner" published in the IDMA Bulletin No. 14 dated 7th November, 2007. Comments / suggestion on the on-line registration were sought for from the industry / trade on behest of the Department of revenue, Ministry of Finance. The comments / suggestions, if any, received from the industry / trade in this regard may please be forwarded to the Narcotics Commissioner, Central Bureau of Narcotics, 19 The Mall, Morar, Gwalior (Madhya Pradesh), Fax: 0751 2368111; email : narcom@sancharnet.in at the earliest.

Source: *IDMA Bulletin XL (21) 7th June 2009*

TB Research Centre in Chennai begins Phase - 1 trial of Prime Boost AIDS Vaccine

The Tuberculosis Research centre (TRC) in Chennai has started the process of phase-1 trial of Prime-Boost Aids Vaccine and has enrolled the first volunteer on April 1. The volunteer got the first of the four doses, said Dr. V D. Ramanathan, Research Scientist in the TRC. He said a simultaneous trial will also be held at the National AIDS Research institute, Pune.

Dr. Ramanathan, Senior deputy director of the Institute said healthy individuals between the age of 18 and 50 who are at low risk for getting HIV infection have been selected as volunteers. No AIDS patient has been selected for the phase 1 trial.

He said that since the phase -1 trial continues for around two years time to get a clear cut result, the time of the phase -2 trials cannot be determined no. The phase -2 depends up on the result of the first one, he added. National AIDS Research Institute (NARI), pune and TRC Chennai are the two sites where the study is being conducted at present. The US-based International AIDS Vaccine Initiative and YRG Care Centre, Chennai are associating with TRC in the research and trials.

For the phase -1 trial strategy, ADVAX, a DNA based vaccine is used as the prime and MVA based vaccine (a vector that contains six HIV genes) is taken for the boost. Dr. Ramanathan clarified that MVA was considered to accept as boost, because of the fact that it would be possible to boost the level of immune response produced by ADVAX.

To complete the trial, thirty two volunteers will be recruited with 16 each at NARI and the TRC. At each centre, the 16 volunteers will be divided into two wings of eight each. One will get only MVA while the other will get ADVAX and MVA (prime Boost). Two volunteers in each will get a placebo, Dr. Ramanathan explained.

He said, earlier the TRC had successfully conducted phase-1 trials of an MVA-based AIDS vaccine candidate (TBC-M4), which indicated that the vaccine candidate had acceptable levels of safety and was well tolerated. The trial was conducted under the aegis of an MoU between the Government of India-through ICMR, NACO and IAVI. But the decision to conduct a phase 1 trial using MVA was dropped and a strategy for using prime boost was considered.

TRC has been developed as a global centre of excellence for clinical evaluation of AIDS vaccines in India. The Vaccine Trial Centre (VTC), established at TRC, includes a clinical facility, a data management unit and a state-of-the-art HIV immunology, virology and routine medical laboratory.

Source: *IDMA Bulletin XL (17) 7th May 2009*

Indian Pharma R&D to touch $1bn: E&Y

The Indian pharmaceutical industry is likely to develop its first indigenous drug in the next two four years and the total investments in R&D is expected to touch over $1billion by 2015, consultancy firm Ernst & Young has said.

"Some (India) companies have molecules in phase III clinical trials and once its growth is planned then once expect an indigenous NCE commercialized molecule launch in the next 2-4 years," Ernst 7 Young partner health sciences practice Ajit mahadevan said.

At present, Indian companies have around 66 new chemical entities (NCE), of which nearly 40 are in the pre-clinical stage development, he said. According o mahadevan, the total investment in Research and Development (R&D) in the pharmaceutical sector is likely to touch over one billion dollar by 2015.

"Key Indian pharma companies are significantly revamping their R&D plans and are likely to spend more than a billion dollars on NCE research by 2015," he said.

According to industry experts, the total investment in R&D in India was $495 billion in 2006and has grown at a compounded annual growth rate of 38 percent per annum between 2001 and 2006.

Meanwhile, Piramal Healthcare Director Swati Piramal has said the entry of first Indian molecule would enhance the image of the domestic industry globally and would completely change its face.

Echoing the similar sentiments, Indian pharmaceutical Alliance Secretary General D G Shah said:"Entry of first Indian drug would garner a respect for the domestic industry, which is generally regarded as the copycat of drugs. "Though Indian pharma companies are no match in term of the financial muscle with multinational pharmaceutical companies.

They nevertheless enjoy advantages of the cost competitiveness, access to large talent base and vast patient population for clinical development, he said.

Source: *IDMA Bulletin XL (22) 14th June 2009*

Roche slashes prices of Actemra drug on customs duty cut

Less than a month after duty cuts on life-saving drugs were announced in the Union Budget, the Swiss pharma giant Roche has taken the first steps in passing on the cost benefit to the patient by slashing prices of Actemra, a drug used in the treatment of rheumatoid arthritis.

The company even announced that the price cuts on the existing stock with its stockists and chemists.

"The government proposed the customs duty cut after representation from the industry and so we decided that we would put it into effect immediately even for stock on which the customs was paid. The hit that we are taking on this front will reduce the cost of Actemra for patients from Rs. 4.5 lakh per year to Rs. 3.2 lakh per year," said Roche Managing Director Girish Telang.

Actemra, a drug which helps preserve joints of people affected with rheumatoid arthritis, was launched almost six months ago and a 22% custom duty was levied on it. A 50% reduction in customs duty for life saving drugs has brought down the duty to 11% for this medicine.

The Basel, Switzerland-based pharma major has also decided to reduce the price of Valcyte and pass on the benefit of a 35% savings to the customer.

The new prices will come into effect from August 1. Valcyte is used to treat and prevent Cytomegalovirus (CMV) infections and CMV retinitis in HIV patents.

Roche also plans to use the savings from the customs duty cuts to expand its cost-assistance access programme.

"We partner with doctors and based on their recommendations we provide assistance to patients who are on the drug but are unable to complete a course due to financial constraints. About 30% of the patients who are on our drugs are part of our access programme," Mr. Telang said.

The government's proposal to cut customs duty will benefit patients who need medication related to cancer, HIV, transplant medication, strong antibiotics and other unmet medical needs. However, with most companies already well stocked with their products it remains to be seen when the actual benefit of the customs cut will kick in.

Source: *The Economic Times, 3rd August 2009*

Rs. 20L Tamiflu seized in Chennai

The Tamilnadu Drugs Control Authority (TNDCA), in a surprise raid seized drugs worth Rs. 40 Lakh, including Rs. 20 lakh worth of Tamiflu, the drug for H1N1 flu from a company in the city on Friday.

Sale of Tamiflu is banned as only the government is entitled to prescribe and distribute the drug. This is to make sure that all cases of H1N1 flu get reported and also because taking the drug unnecessarily would lead to the virus developing immunity to it.

According to officials, the Tamilnadu Government received information that drugs meant for H1N1 flu were stocked in some places. The TNDCA was ordered to crack down on them. The TNDCA raided the premises of TDP Technology on Lyods Road and found Rs. 20 lakh worth of anti-flu capsules (Oseltamivir phosphate). Cipla is the manufacture of the anti-flu drug.

The drug is meant for export and not for sale in India. The medicine should have been directly sent to the country which orders them and there should not be any dealers in between. In this case, the drugs were sent to TDP Technology from a Mumbai-based company called Euphoria Health Care. Further investigation is on.

Officials state that this is a violation of the Drugs and Cosmetics Act. Earlier, Director of Public Health Dr. S. Elango had issued circulars making it mandatory for doctors to report the flu if they diagnose it.

Director of Drugs Control, Dr. M. Baskaran had told pharmacies not to sell the drug. Action against erring pharmacies would include suspension of their license. "Taking the pill renders the drug useless in case a person gets affected by the virus. It could prove fatal," Dr. Baskaran said.

Source: *Times of India, 28th June 2009*

FORTHCOMING EVENTS

Capacity Building National Workshop for Monograph Development for Herbals

21 - 22 August, 2009, Mumbai
Organized by
Indian Pharmaceutical Association (IPA)
Jointly with
National Medicinal Plant Board (NMPB)
In collaboration with
Indian Pharmacopoeia Commission (IPC)

For further details contact:
Mr. T. B. Nair
Executive Secretary
The Indian Pharmaceutical Association
Kalina, Santacruz,(East), Mumbai 400 098.
Telefax: 022 2667 0744 **Telephone:** 022 2667 1072
Web site: www.ipapharma.org
E mail: ipacentre@ipapharma.org

Engimac Industrial Exhibition

24 - 27 July, 2009, Pragati Maidan, New Delhi

For further details contact:
K. and D Communication Limited
4th Floor, Chinubhai house
7-B, Amrutbaug Society, Opp. Hindu Colony
Nr. Sardar Patel Stadium, Navrangapura
Ahmedabad, - 380 014., Gujrat
Telphone: 91 79 2646 9725, 2646 0624, 2646 0453
Fax: 91 79 2640 3087
E Mail: info@engimac.com, imtos@imtos.com
Web Site: www.imtos.com

Source: *Pharma Times, Vol 41, No. 5, May 2009*

AICTE sponsored National Seminar on

Brand Management in Pharmaceutical Industry: Critical Issues and Ethical Concerns

3 - 5 August, 2009
&
Staff Development Programme
6 20 August, 2009

For further details contact:
Manipal College of Pharmaceutical Sciences
(Constituent College of Manipal University)
Manipal - 576 104, Karnataka, India.
Web site: www.manipal.edu/mcops

Two days professional development programme on

Modern Trends in Pharmacy Practice

In association with AICTE
28 - 29 August, 2009

Venue: Amrita Institute of Medical Sciences, Kochi, Kerala
Email: pharmacycollege@aims.amrita.edu
Website: www.amrita.edu

Source: *IPA website*

FIP World Congress of Pharmacy and Pharmaceutical Sciences

3 - 8 September, 2009, Istanbul, Turkey

Web site: http://fip.org/istanbul2009

PSG Institute of Medical Sciences and Research

Two pre- conference workshops

12 - 14 November, 2009

Venue: PSG Health Institutions
E mail: srips2009@gmail.com
Web site: www.psgimsr.in

Source: Pharma Times, Vol 41, No. 6, June 2009

Indian Pharmaceutical Congress

11 - 13 December, 2009, Ahmedabad

Theme: PHARMA VISION 2020 BUILDING TRUST IN SAFETY AND EFFICACY OF MEDICINES

2nd IPA National Convention, March 2010

Organised by IPA TN Branch

For further details contact:
The Secretary IPA ,TN Branch
"Sridevi Temple Towers"
Survey No. 135 / 1B, Sembakkam 2nd Main Road
Sembakkam, Chennai 600 073.

OBITUARY

DEMISE Dr. M. Venkateswarlu, Drugs Controller General of India, (Rtd.)

We regret to inform sad demise of Dr. M. Venkateswarlu, Rtd. Drugs Controller General of India on Sunday, 28th June 2009. He was an experienced Drug regulator and an expert on Drug Regulatory and Quality Assurance matters. He had served the Central Drugs Standard Control Organization, Ministry of Health & Family Welfare for more than three decades. Dr. Venkateswarlu was holding a Doctorate degree in Pharmaceutical Sciences from Andhra University.

In his role as the Drugs Controller General of India, Dr. Venkateswarlu had been actively involved in the implementation of the provisions of the Drugs & Cosmetics Act and Rules. He was an expert in conducting GMPs, GCPs and GLPs Audits.

His key achievements involved upgradation of the existing GMP standards and the requirements of the Government of India to that of global standards. He has also been responsible for the upgradation of requirements for introduction of New Drugs and Investigational New Drugs. Dr. Venkateswarlu had been instrumental in facilitation Global Clinical Trials in India and framing guidelines for CROs. He had put in a significant effort in weeding out fixed-dose combinations whose rationality, safety and efficacy are not established from the market. As the Chairman of Indian Foundation of Pharmaceutical Reference Standard Substances (IFPRESS), he worked towards making IP certified Reference substances available to the drug industry.

He was an expert member of "IP Reference Substances Committee" of the new edition of Indian Pharmacopoeia. He had also served as a Member Secretary for major committees involved in connection with Drugs Legislations, e.g. API, DMF, Schedule M, Medical Devices, LVP Loan Licenses, etc. He had participated as an observer from India for the ICH Expert Working Group on GMP for API. He had also been associated with various professional bodies in administrative capacities like the IPA Regulatory Affairs Division, AIDCOC, Pharma Times, IFPRESS, USP-GCQ India, ISPE, HADSA.

He had been actively involved in Drug Inspectors Training Scheme till January 2008. He was a regular faculty member for training programmes conducted by CDSCO and for various University courses.

Dr. Venkateswarlu held to his credit, distinguished awards for his excellence and contribution to the Indian Drug Regulatory system such as the Best Drug Control Officers Award in the Year 2001 by AIDCOC, Mumbai, and Fellowship Award in the Year 2002 by the IPA, Mumbai and Excellence in Regulatory Sciences award 2006 by the IDMA. In 2007, Dr. Venkateswarlu has been awarded the life time achievement award for contribution to the Drug Regulatory Authority by the 59th IPC. He had featured in the World Frontier's 40 most influential people of the pharmaceutical Industry in the year 2006 & 2007 on Rank 22 and Rank 16 respectively.

He had authored various publications like IDMA Bulletin, Express Pharma Pulse, Pharmabiz, Heritage Healing, AAIPS & AIDCOC. He had also participated &presented papers in International forums.

Our heart felt condolence to the family members of Dr. Venkateswarlu. We pray his soul rest in peace.

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MANAGING DIRECTOR,

Joint Director of Industries and Commerce (Retd.)

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- ENTREPRENEUR DEVELOPMENT TRAINING PROGRAMMES
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