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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

April - May - June. 2012

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Tamilnadu Pharmaceutical
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EDITORIAL

Dear Readers,

We are happy to release 14th issue of **Pharma Web** for the period April-June 2012. Our Chief Editor Mr. Narayanaswamy is on a holiday at USA with his son , I have therefore been entrusted the pleasant task of penning the editorial for this issue.

We are happy to inform , that shortly our trust office is going to get renovated in order to give you all a much better atmosphere with a new comfortable Conference Hall and other improved facilities. We should thank our Chairman Mr. S. V. Veerramani for mooting the idea of renovation.

In this issue we reproduce two papers published in the **Indian Journal of Natural products and-Resources Viz. ethano medicinal plants used for the treatment of Diabetes and Jaundice by Palliyar Tribals in Sirumalai Hills, Western Ghats, Tamil Nadu** of Ethano Pharmacology Unit, PG & Research , Dept of Botany, V.O. Chidambaram College, Tuticorian and Myrtus Communis Linn – A Review by Dept of Ilmul Advia (Pharmacology) ,Faculty of Unani Medicine, Hamdard University, New Delhi . We wish to convey our sincere thanks for the kind permission given by them for reproduction.

Gazette Notification containing the draft of Rules to **amend the Drugs and Cosmetics Act 1945** and second prized essay competition on **I am a Pharmacist- Why?** By Ms. Divya , Final B.Pharm of Vels College of Pharmacy, M.Pharm Scholarships awarded by the Trust for the year 2011-2012 (Profile of 2nd Rank Projects), Information , Events and News are the other regular features that appear in this issue.

We have requested our readers to give their views and comments about the contents and usefulness of **Pharma Web** , but sorry to say that we have not received any response from you so far. Our request continues once again. Your views will help us to improve the contents of our future Issues.

We have just received the happy news that the 64th Indian Pharmaceutical Congress will be held at Chennai from 7th to 9th Dec 2012 under the President ship of Prof. K. ChinnaSwamy.

With best regards

K. Prafulla Chandra

(Associate Editor)

ARTICLES

Ethnomedicinal plants used for the treatment of diabetes and jaundice by Palliyar tribals in Sirumalai hills, Western Ghats, Tamil Nadu, India

By

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The study has been carried out in Sirumalai hills of Western Ghats, Dindigul district, Tamil Nadu. Palliyar, the predominant tribal community has their settlements in different areas in the Sirumalai hills. 30 medicinal plants belonging to 18 families are identified which have been employed by the tribal community for the treatment of diabetes and jaundice. Theplants have been tabulated with botanical, family and vernacular names, mode of use and dosage, etc.

Keywords: Diabetes, Ethnomedicine, Jaundice, Palliyars, Sirumalai hills, Western Ghats.

IPC code; Int. cl. (2011.01) - A61K 36/00, A61P 1/16, A61P 3/10

Introduction

Diabetes mellitus remains a global major health problem in the World over with the tropics inclusive. In the past decade, the United States have recorded a 33% rise in the cases of diabetes1. Diabetes is a complex and multifarious group of disorders characterized by hyperglycaemia that has reached epidemic proportions in the present century. Several drugs such as biguanides and sulfonylureas are presently available to reduce hyperglycaemia in diabetes mellitus. These drugs have side effects and thus searching for a new class of compounds is essential to overcome these problems2. Management of diabetes without any side effects is still a challenge to the medical community. There is continuous search for alternative drugs. Therefore, it is prudent to look for options in herbal medicine for diabetes as well3. Jaundice is not a disease but rather a sign that can occur in many different diseases. Jaundice is the yellowish staining of the skin and sclera (the whites of the eyes) that is caused by high levels in blood of the chemical bilirubin. The colour of the skin and sclera vary depending on the level is mildly elevated, they are yellowish. When the bilirubin level is high they tend to be brown4. The manifestation of liver diseases such as hepatitis-B including jaundice, characterized by Hippocrates was found to be infectious as early as the eighth century. Thus, viral hepatitis was known to mankind as Kavil (Jaundice) for more than 1,200 years. Yellowing of eyes and vomiting yellowish fluid are the initial external symptoms of hepatitis5,6.

The Palliyars are the predominant hill tribe of Sirumalai hills, Dindigul district, Western Ghats, Tamil Nadu. They are familiar with several herbs and well-versed in using herbs to cure various ailments. Their reliance on the herbs for medicinal value has prompted the present study. Some information on ethnomedicinal plants used by different tribals of Western Ghats for treating various ailments is available7-10. In the present study an attempt is made to bring into light the traditional medicinal practices adopted by this section of tribal community to ensure diabetes and jaundice.

Materials and Methods

The study area Sirumalai hills is located in Dindigul district of Tamil Nadu between 10°.07′-10°.18′N latitude and 77°.55′-78°.12′ E longitude. With the primary objective of interacting with the

Palliyar tribes settlements like Ooradi, Madagamalai, Ponnuruvi, Kannadiparai and Talaikadu of Sirumalai hills were surveyed and information was gathered by interviewing elderly and experienced individuals practicing indigenous medicine for diabetes and jaundice. Information was considered only after confirmation through two or more informants. on the information provided, plant specimens were collected, air-dried and mounted on herbarium sheets and identified by using various floras. Voucher specimens are maintained at Ethnopharmacology Unit, Research Department of Botany, V.O.Chidambaram College, Tuticorin, Tamil Nadu, India.

Results and Discussion

The botanical name, family, vernacular name, part(s) used, mode of use, dose and duration are given in Table 1. The present study has documented 30 species of angiospermic plants, belonging to 30 genera under 18 families, used by Palliyar tribe of the state for treatment of diabetes and jaundice (Plate 1). Of the 30 species, 19 species belonging to 13 families are used by the Palliyars to treat against diabetes. The remaining 12 species belonging to 7 families are used to treat against jaundice. Medicines are prepared in the form of juice/extract followed by infusion, powder, decoction, paste and as such. Among different plants used by Palliyar, the leaves are more commonly used. During the survey it was observed that some plants are used alone while some in combination with other plant parts.

Table 1 - List of ethnomedicinal plants used by Palliyars to treat diabetes and jaundice

S.No.	Botanical name / Voucher specimen No.	Vernacular name	Family	Mode of use
A. Diabetes				
1.	Azadirachta indica A. Juss / VOCB 5442	Vempu	Meliaceae	30 ml of juice prepared from the tender leaves with an unripe fruit of Terminalia chebula Retz. (Kadukkai) is taken along with a teaspoon of castor oil (oil obtained from the seeds of Ricinus communis Linn.) twice a day for a period of one week as an anthelmintic (de-wormer). It is also mixed with honey, cow's milk, butter and ghee and taken twice a day for a period of forty five days to treat diabetes.
2.	Casearia tomentosa Roxb. / VOCB 5478	Kadaka kinchil	Flacourtiaceae	30 ml of the boiled water extract of the root bark is taken to treat diabetes.
3.	Cassia fistula Linn./VOCB 5469	Semaiagathi	Caesalpiniaceae	20 ml of the boiled water extract of the flowers is taken twice a day regularly by diabetic patients to reduce the blood glucose level.

S.No.	Botanical name / Voucher specimen No.	Vernacular name	Family	Mode of use
4.	Catharanthus roseus (Linn.) G. Don/ VOCB 5472	Palaisethai	Palaisethai	20 ml of the boiled water extract of flowers is taken thrice a day for a period of one month to treat diabetes.
5.	Coccinia grandis (Linn.) Voigt/VOCB 5487	Kovai	Cucurbitaceae	Two fresh fruits are taken regularly to prevent diabetes.
6.	Dichrostachys cinerea (L.) Wight & Arn. /VOCB 5511	Vedathalan	Mimosaceae	30 ml of the juice prepared from 15 g of the fresh leaves along with the fresh leaves of Limonia acidissima Linn. (Vila) and Cocculus hirsutus (Linn.) Diels (Sirukattunkodi) and the stem bark of Senna auriculata Linn. (Avarai) is taken with buttermilk once a day.
7.	Ficus benghalensis Linn./VOCB 5527	Alamaram	Moraceae	100 g of the dried stem bark and root bark are continuously boiled in 250 ml of water with 50 g of the dried stem bark of Ficus hispida Linn. f. (Peiathi). The decoction obtained is taken once a day for a period of six weeks to treat diabetes.
8.	Garuga pinnata Roxb./VOCB 5534	Karuvembu	Burseraceae	A handful of fresh stem bark is boiled in 100 ml of water with few dried leaves of Gymnema sylvestre (Retz.) R.Br. ex Schultes (Sirukurinjan). The decoction obtained is taken twice a day for a period of seven weeks to treat diabetes. Consumption of acidic food items, meat and sugar is avoided during the treatment period.
9.	Gymnema sylvestre (Retz.) R.Br ex Schultes / VOCB 5541	Sirukurinjan	Asclepiadaceae	One teaspoon of the powder made from the dried leaves and the flowers of Cocos nucifera Linn. (Coconut) is taken with hot water once a day for a period of one month to treat diabetes.

S.No.	Botanical name / Voucher specimen No.	Vernacular name	Family	Mode of use
10.	Hemidesmus indicus (Linn.) R. Br./VOCB 5544	Nannari	Asclepiadaceae	The root infusion is taken twice a day for a period of six weeks to treat diabetes.
11.	Hybanthus enneaspermus (Linn.) F.V. Muell./VOCB 5548	Orilai thamarai	Violaceae	20 ml of the whole plant juice is taken with cow's milk for a period of four to five months to treat diabetes.
12.	Mallotus philippensis (Lam.)Muell.-Arg./VOCB 5567	Kabila	Euphorbiaceae	Few fruits are boiled in 200 ml of cow's milk with few seeds of Syzygium cuminii (Linn.) Skeels (Naval). The decoction obtained is taken twice a day for a period of one month to treat diabetes.
13.	Momordica charantia Linn./VOCB 5579	Pakarkai	Cucurbitaceae	30 ml of the juice prepared from few fresh fruits and few fresh leaves with pieces of the stem bark of Syzygium cuminii is taken once a day to treat diabetes.
14.	Pongamia pinnata (Linn.) Pierre/VOCB 5609	Pungam	Fabaceae	The flowers are fried in ghee and taken with honey thrice a day to treat diabetes.
15.	Premna latifolia Roxb./VOCB 5613	Pachu mallai	Verbenaceae	30 ml of the leaf juice is taken with a glass of cow's milk twice a day to treat diabetes.
16.	Pterocarpus marsupium Roxb./VOCB 5616	Vengai	Fabaceae	20 ml of the hot water extract of the stem bark/wood is taken twice a day to treat diabetes
17.	Senna auriculata (Linn.) Roxb./VOCB 5625	Avarai	Caesalpiniaceae	30 ml of the boiled water extract of the roots is taken twice a day for a period of one month to treat diabetes.

S.No.	Botanical name / Voucher specimen No.	Vernacular name	Family	Mode of use
18.	Syzygium cuminii (Linn.) Skeels/VOCB 5636	Naval	Myrtaceae	1. 30 ml of the hot water extract of the seeds is taken twice a day for a period of one month to treat diabetes. 2. An ounce (c. 28 g) of the hot water extract of the stem bark is taken twice a day for a period of forty five days to treat diabetes.
19.	Wattakaka volubilis (Linn.f.) Stapf./VOCB 5653	Kurinjan	Asclepiadaceae	One teaspoon of the leaf powder is taken regularly with water to treat diabetes.
B. Jaundice				
20.	Aegle marmelos (Linn.) Correa ex Roxb./VOCB 5413	Villvam	Rutaceae	A blend of juice prepared from 5 g of the fresh leaves along with 5 g of the fresh leaves of Eclipta prostrata (Linn.) Linn. (Karisalankanni) is taken with honey twice a day for a period of 2 weeks to treat jaundice.
21.	Boerhavia diffusa Linn./VOCB 5451	Mookaratti	Nyctaginaceae	One teaspoon of the leaf paste is taken twice a day for period of one week to treat jaundice.
22.	Cajanus cajan (Linn.)Millsp./ VOCB 5460	Thuvarai	Fabaceae	30 ml of the salted boiled water extract of the fresh leaves is taken in empty stomach for a period of 2 weeks to treat jaundice.
23.	Cassia fistula Linn./VOCB 5469	Semaiagathi	Caesalpiniaceae	One teaspoon of leaf and flower powder is taken with a glass of cow's milk once a day for a period of 2 weeks to treat jaundice.
24.	Eclipta prostrata (Linn.) Linn./ VOCB 5517	Karisalangk-anni	Asteraceae	The leaves boiled in hot water combined with extracts of Leucas aspera (Willd.) Link (Thumbai) and Phyllanthus amarus Schum. & Thonn. (Keela nelli) is taken withbuttermilk twice a day for a period of one week to treat jaundice.

S.No.	Botanical name / Voucher specimen No.	Vernacular name	Family	Mode of use
25.	Euphorbia nivulia Buch.-Ham./VOCB 5525	Kalli	Euphorbiaceae	20 ml of the salted leaf extract is taken for a period of one week to treat jaundice
26.	Glycosmis pentaphylla (Retz.)DC./ VOCB 5537	Kulaparai	Rutaceae	One teaspoon of the leaf powder is taken with honey twice a day for a period of 2 weeks to treat jaundice.
27.	Indigofera tinctoria Linn./ VOCB 5551	Kattavuri neeli	Fabaceae	The leaf infusion in goat's milk is taken in the early morning hours for a period of 2 weeks to treat jaundice.
28.	Phyllanthus amarus Schum. &Thonn./ VOCB 5600	Keela nelli	Euphorbiaceae	30 ml of the extract obtained by squeezing some tender leaves together with few tender leaves of Eclipta prostrata and Leucas aspera (Thumbai) is taken with cow's milk twice a day for a period of 2 weeks to treat jaundice.
29.	Phyllanthus emblica Linn.= Emblica officinalis Gaertn./VOCB 5601	Nelli	Euphorbiaceae	The decoction obtained by continuously boiling some shade dried fruits, few shade dried leaves of Alternanthera sessilis (Linn.) R. Br. ex DC. (Ponnankanni keerai), few fresh roots of Glycyrrhiza glabra Linn (Adhimathuram), few cardamom [seeds of Elettaria cardamomum (Linn.) Maton], few seed kernels of Myristica fragrans Houtt. (Jathikkai) and one or two pericarp of Terminalia bellirica (Gaertn.) Roxb (Thandri) in 200 ml of diluted cow's milk is taken twice a day for a period of 2-3 weeks to treat jaundice.
30.	Polycarpaea corymbosa (Linn.) Lam./VOCB 5608	Palli poondu	Caryophyllaceae	One teaspoon of the leaf paste is taken once a day for a period of 2 weeks to treat jaundice.
31.	Ricinus communis Linn./VOCB 5620	Amanakku	Euphorbiaceae	One teaspoon of the blend made by grinding some shade dried leaves and few shade dried leaves of Phyllanthus amarus (Keelanelli) is taken with ghee thrice a day for one week to treat jaundice.

Casearia tomentosa

Dichrostachys cinerea

Euphorbia nivulia

Garuga pinnata

Gymnema sylvestre

Hemidesmus indicus

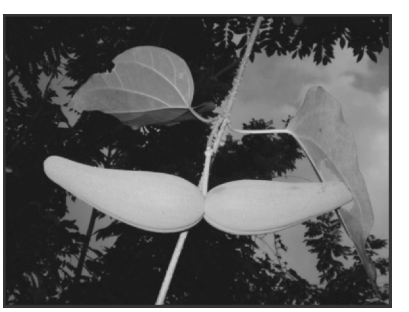
Hybanthus enneaspermus

Mallotus philippensis

Polycarpaea corymbosa

Pterocarpus marsupium

Syzygium cuminii



Wattakaka volubilis

Plate 1 - Some important ethnomedicinal plants of Sirumalai hills used by Palliyar tribes

The medicinal plants used by the Palliyars need to be systematically screened by phytochemists and pharmacologists for the potent active principles. Scientific validation of these remedies may help in discovering new drugs from these medicinal plants for diabetes and jaundice.

Conclusion

In the present study 30 angiosperm species belonging to 18 families collected from Sirumalai hills, Dindigul district, Tamil Nadu have been reported for treating diabetes and jaundice. This study reveals that medicinal plants still play a vital role in the primary healthcare of this tribal community. Traditional medicines also have the potential to form the basis of pharmaceutical drugs for the treatment of a range of diseases. Thus, the loss of these potentially valuable genetic resources ultimately affects the whole society. There is an urgent need to document the knowledge or otherwise it is lost forever.

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Myrtus communis Linn. - A review

By
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Myrtus communis Linn. or common Myrtle (Family ¾ Myrtaceae) is one of the important drugs being used in Unani System of Medicine since ancient Greece period. It is recognized as Aas and its berries are known by the name of Habb-ul-Aas. It is often grown for its attractive foliage, flowers and berries. Its berries, leaves as well as essential oil are frequently used for various ailments like gastric ulcer, diarrhoea, dysentery, vomiting, rheumatism, haemorrhages, deep sinuses, leucorrhoea and cosmetic purposes like hair fall control. The leaves, berries and twigs are used in flavouring of food and wines. In past times, ripe fruits were used as food integrators because of their high vitamin contents. A wide range of biologically active compounds such as tannins, flavonoids, coumarins, essential oil, fixed oil, fibres, sugars, citric acid, malic acid and antioxidants are present in the plant. This contribution provides a comprehensive review of its ethno-medical uses, chemical constituents and pharmacological profile as a medicinal plant.

Keywords: Aas, Common Myrtle, Habb-ul-Aas, Myrtus communis, Myrtaceae, Phytochemical constituents, Traditional medicine.

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Introduction

Myrtus communis Linn. (Family - Myrtaceae) is an aromatic evergreen perennial shrub or small tree, 1.8-2.4 m in height with small foliage and deep fissured bark (Plate 1). It is native to Southern Europe, North Africa and West Asia. It is distributed in South America, North western Himalaya and Australia and widespread in the Mediterranean region. It is also cultivated in gardens especially North-west Indian region for its fragrant flowers[1,2]. Myrtus, the Greek name for Myrtle and communis means common plant growing in groups. The first reference of Myrtle in the Bible is in Nehemiah 8:15 in regard to the celebration of the feast of Tabernacles. The common Myrtle was introduced into Britain in around 1597 and was described by Linnaeus in 1753. Myrtle occupies a prominent place in the writings of Hippocrates, Pliny, Dioscorides, Galen and the Arabian writers[3,4].

The common myrtle has upright stem, 2.4-3 m high, its branches form a close full head, thickly covered with evergreen leaves. The stem of the plant is branched and dark green leaves are glossy, glabrous, coriaceous, opposite, paired or whorled,

ovate to lanceolate with stiff structure, aromatic, entire margined, acuminate and 2.5-3.8 cm long, glands absent in the lamina. It has axillary white flowers on slender peduncles, medium sized about 2 cm in diam., stiff having yellow anthers. The petals are pure white with glands and somewhat tomentose margin covered with fine hairs. They give off a sweet fragrant smell. The berries are pea-sized, orbicular or ovoid-ellipsoid, blue-black or white with hard kidney shaped seeds. They are of varying sizes (0.7-1.2 cm) and shapes. The glabrous berry has rounded (vaselike) shape with a swollen central part and remnants of persistent 4-5 partite calyx at the outer part. The developed fruit is initially pale green, then turns deep red and finally becomes dark indigo when fully mature. They are bitter when unripe, sweet when ripe. It is highly drought tolerant and needs only little to moderate water. Soil should be allowed to dry in-between watering. It can grow in damp places, shades as well as full sun up to 800 m altitudes. Its blooming time is summer[2-7].

Medicinal and other uses

Berries are used as antiseptic, astringent[1], carminative[1,3,5], emmenagogue[1,3], demulcent, dessicant, analgesic, hair tonic, haemostatic[8], antiemetic, lithotripsic[9], cardiotonic, diuretic[3,9,10], anti-inflammatory[11], stomachic, brain tonic[3,9], haemostatic, nephroprotective, antidote[11], antidiaphoretic[10] and antidiabetic[12]. Various pharmacological actions of leaves are astringent, antiseptic[1], hypoglycaemic, laxative[12], analgesic[3,10], haemostatic[10], hair tonic[8,13] and stimulant[1]. Root is reported to have antibacterial property[14].

It is traditionally used as an antiseptic, disinfectant drug and hypoglycaemic agent[15]. Different parts of the plant have been used in the food industry, for example for flavouring meat and sauces, and in the cosmetic industry[16]. Dioscorides described the preparation of its oil and prescribed an extract in wine for lung and bladder infections. Foods flavoured with the smoke of myrtle are common in rural areas of Italy or Sardinia[17,18]. In folk medicine, a decoction of leaves and fruits is used as stomachic, hypoglycaemic, antimicrobic, cough and oral diseases, for constipation, appetizing, antihemorrhagic and externally for wound healing[19]. The essential oil of the leaves has been esteemed in France as a disinfectant and useful antiseptic, also used in Paris hospitals in certain respiratory and bladder diseases and recommended as a local application in rheumatic disease[1,3,5,20]. The fruit decoction was used to bath new-borns with reddened skin, while the decoction of leaves and fruits was useful for sore washing. The decoction of the leaves is still used for vaginal lavage, enemas and against respiratory diseases[11]. A fixed oil obtained from berries strengthens and promotes growth of hair due to hair tonic property[1,13,21]. Consumption of myrtle can probably offer some dietary benefits, as they contain antioxidant constituents, which can protect against lipid peroxidation and can scavenge free radicals[19]. In earlier times, ripe fruits of myrtle were used as food integrators because of their high vitamin contents[20]. The therapeutic dose of berries of M. communis mentioned in Unani literature is 3 to 5 grams[9-11]. The berries are used in diarrhoea, dysentery, internal ulceration, rheumatism[3,21], foot ulcers, foetid ulcers, aphthae, deep sinuses, hairfall, haemorrhages, leucorrhoea, lax vaginal walls1, bronchitis[3], haemorrhoids[22], malaena, rhinitis, rectitis, conjuctivitis, piles, burns, dysurea, cough, epistaxis[10], earache, toothache, headache, palpitation[23], otorrhea[24], sprain, fractures, fever, polydipsia, burning micturition, scorpion sting, dandruff, melasma cholasma, menorrhagia, haemoptysis, uterine prolapse, rectal prolapse, eye ulcers, halitosis (bad breath), head ulcers, vomiting, inflammations[8] and gastric ulcer[25]. The leaves are useful in cerebral diseases especially epilepsy, stomach diseases[5,22], dyspepsia, liver diseases, rheumatism[3,22], aphthae, eczema, pulmonary disorders[5,14], piles, sores[3], intertrigo, wounds, ulcers[1], stomatitis, deep sinuses, uterine prolapse, leucorrhoea, stomatitis, internal ulceration, haemorrhage[2], inflammation, diarrhoea, hair fall, burns, herpes, palpitation, mennorhagia8, chronic bronchitis[12], abscess, sprain, diaphoresis[24] and chronic catarrah of bladder[26].

Phytochemical constituents

The plant contains fibres, sugars and antioxidants and many biologically active compounds[27,28]. Phenolic compounds, flavonoids and anthocyanins are the major phytochemicals in berries. Seeds yield 12- 15% of a fatty oil (fixed oil) consisting of glycerides of oleic, linoleic, myristic, palmitic, linolenic and lauric acid[5,29]. Studies on fatty acid analysis of myrtle fruits showed that it contains 14 fatty acids, oleic acid being the dominant fatty acid (67.07%) followed by palmitic acid (10.24%) and stearic acid (8.19%)[30]. Myrtle oil is the essential oil of M. communis, which is extracted from the leaves, branches, fruits and flowers through steam distillation[1,5]. It is yellow or greenish yellow in colour with a characteristic refreshing odour. The yield and quality of oil depends upon the region of production, the season of harvest and the length of distillation. The oil yields (w/w) of different parts of plant are different. The yields of the hydrodistilled oils are: leaves, 0.4-0.5; flower, 0.4; unripe fruits, 0.5; and ripe fruits, 0.02%. Terpenes and terpene alcohols make up nearly the whole of the volatile compounds of the essential oil31. The five terpenoid compounds (myrtenyl acetate, 1, 8-cineole, limonene, linalool) are present in leaf oil (0.19-0.37%), fruits (0.03-0.13%) and flowers (0.21-0.26%) but in different propotions[32].

Composition of essential oil is: 1, 8-cineole, -pinene, methyl eugenol, terpineole, trans-carveole, cis-carveole, geraniol, methyl geranate, -terpinyl acetate, neryl acetate, -caryophyllene, myrcene, sabinene, myrcene, p-cymene, c-terpinene, linalyl acetate[24], car-3-ene, phellandrene, methyl eugenol[33], methyl butyrate, methyl benzoate, benzyl alcohol, isobutyl butyrate[31], myrtenylacetate[32], limonene, -terpineol, linalool[32,24], eucalyptol[34,35], p-cymol, -pinene[36], geraniol, camphene, butyl butyrate and myrtenol[2].

Berries are reported to contain citric acid, malic acid, resin, tannin, fixed oil[1,5], sugar1, flavonoids, anthocyanin arabinosides, anthocyanin glucosides[36], kaempferol, quercetin, myricetin 3-o-glucoside, myricetin 3, 3-di-o-galactoside, myricetin 3 rutinoside, aesculin, scopoletin, caffeic acid[37], myricetin 3-o-rhamnoside or myricitrin, esculetin-6-oglucoside or esculin, hesperetin 7-o-rhamnoglucoside or hesperidin, hesperetin-2-o-methylchalcone-4 orhamnoglucoside[38]. Leaves contain, tannins, flavonoids, coumarins[39], myrtucommulone A & B29, semimyrtucommulone[40], galloyl-glucosides, ellagitannins, galloyl-quinic acids[41], caffeic, gallic and ellagic acids[42]. The roots showed the presence of tannins[23], alkaloids, glycosides, reducing sugars[2], fixed oil[21], gallic acids, phenolic acids, quercetin and patuletin[39].

Pharmacological activities

Antimicrobial

The antimicrobial activity of the crude preparation of Myrtle on Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, P. vulgaris, P. mirabilis, Klebsiella aerogenes, Salmonella typhi and S. shigiella was determined by Alem et al and preliminary study supported its traditional claim of effective anti-infective[43].

Mansouri et al[44] evaluated the antibacterial activity of methanol crude extract of M. communis against 10 laboratory strains of microorganisms, including 6 Gram positive (Staphylococcus aureus, Micrococcus luteus, Streptococcus pneumoniae, S. pyogenes, S. agalactiae and Listeria monocytogenes) and 4 Gram negative bacteria (Escherichia coli, Proteus vulgaris, Pseudomonas aeruginosa and Campylobacter jejuni). The crude extract inhibited the growth of all tested bacteria except C. jejuni[44].

Akin et al[34] also assayed antimicrobial activity of M. communis against seven pathogen bacteria (Staphylococcus aureus, Listeria monocytogenes, Enterococcus durans, Salmonella typhi, Escherichia. coli, Pseudomonas aeruginosa and Bacillus subtilis). It showed some activity on

Gram positive and Gram negative bacteria. The higher efficacy of M. communis was confirmed by the agar dilution method[34].

Two methods were used by Al-Saimary et al to evaluate the antibacterial activity of various concentrations of aqueous extracts of leaves against Pseudomonas aeruginosa with comparison to 6 antibiotics; these methods determine the growth inhibition zones and minimal inhibitory concentration. Aqueous leaves extracts gave an excellent effect on bacterial growth and their effects were located within the limits of antibiotic effects[45].

Appendino et al46 investigated polar glycosidic fraction obtained from the leaves for antibacterial activity and significant antibacterial activity was shown by gallomyrtucommulone. Yadegarinia et al[24] reported excellent antimicrobial activities of oil against Escherichia coli, Staphylococcus aureus and Candida albicans. The essential oil of Myrtle showed good antimicrobial activity against clinical strains of Mycobacterium tuberculosis[47]. The oil also showed significant results against Helicobacter pylori[48].

The methanol, ethanol and ethyl acetate extracts of leaves and berries were examined against food-borne pathogens and food spoilage bacteria, Listeria monocytogenes CECT 4032 and Pseudomonas aeruginosa IH, to determine the effect of the extract on viable counts of bacteria using the bacterial cell-death time. It showed relatively high antibacterial activity against most of the tested microorganisms[49].

Antifungal

The essential oil inhibited (60%) growth of R. Solani at a dose of 1600 ppm in vitro50. Antifungal activity of the essential oil was also studied against Aspergillus by broth microdilution method and found effective against all isolates51.

Activity against Trichomonas vaginalis

To investigate the effect of drugs other than metronidazole, 3 non-pregnant women infected with Trichomonas vaginalis were treated with doxycycline, 2 × 200 mg/day for one week. It caused death of T. vaginalis at pH 4.65, but failed to do so at pH 6.00 (Ref. 52).

Anti-molluscicidal

Crude water extract and flavonoid fraction of M. communis were found to possess molluscicidal activity against the aquatic snail Biomphalaria glabrata involved in the transmission of schistosomiasis[53].

Insecticidal

The insecticidal activities of essential oil from leaves and flowers of M. communis against fourth-instar larvae of the mosquito Culex pipiens molestus Forskal were determined and oils were found to be toxic[54].

The essential oil showed insecticidal activity against 3 stored-product insects, i.e. adults of the Mediterranean flour moth Ephestia kuehniella Zeller, the Indian meal moth Plodia interpunctella Hubner and the bean weevil Acanthoscelides obtectus Say[55].

The essential oils of Myrtle showed insecticidal activity against body lice and nits (Pediculus humanis capitis) when it was tested by using micro atmosphere and distemper methods. Perhaps the activity is due to the presence of Lineol and a-pinene and linalool[56].

Essential oil showed anti-malarial activity against Plasmodium falciparum at concentration ranging from 150-270 μg/ml(Ref. 57).

Anti-inflammatory

Myrtucommulone (MC), semimyrtucommulone (S-MC) and nonprenylated acylphloroglucinols present in the leaves of M. communis, potently suppress the biosynthesis of eicosanoids by direct inhibiting cyclooxygenase-1 and 5-lipoxygenase in vitro and in vivo. Their ability to suppress typical proinflammatory cellular responses

suggested their therapeutic use for the treatment of diseases related to inflammation and allergy[40].

The plant was assessed for the anti-inflammatory activity on rats by measuring the suppression of carrageenan-induced paw edema produced by 1/10 of the intraperitoneal LD50 doses for the respective 80% ethanol extracts. Acetylsalicylic acid was used as the standard drug. Results showed that it possessed anti-inflammatory activity[58].

Antioxidant

The antioxidant activities of the fruit extracts were determined by using 2,2-diphenyl-1 picrylhydrazyl (DPPH) and -carotene-linoleic acid assays. The methanol extracts of fruits exhibited a high level of free radical scavenging activity[19]. In another study antioxidant activity of methanol, ethanol, water and ethyl acetate extracts of the leaves and berries were measured. Antioxidant activity was assessed by measuring the ability of the extracts to scavenge the 2,20-azinobis (3-ethylbenzothiazoline-6-sulphonic acid) diammonium salt (ABTSþ) radical. All of the extracts showed significant antioxidant capacity and higher being in leaves[59].

Flavonoids and anthocyanins in berries extract were checked for antioxidant activity by TEAC assay and the free radical activity. The myrtle extract showed interesting free radical scavenging activity[60].

Radical scavenging activity of essential oil was studied by collecting the plant samples from the two distant localities. Both oils exhibited moderate DPPH (2,2-diphenyl-1-picrylhydrazyl) scavenging activity[61].

Protective effect on cholesterol and human low density lipoprotein (LDL)

Rosa et al[62] reported that semimyrtucommulone and myrtucommulone A extracted from M. communis have significant protective effect on LDL from oxidative damage, remarkable protective effect on the reduction of polyunsaturated fatty acids and cholesterol and inhibiting the increase of their oxidative products. Both the compounds have been suggested as natural dietary antioxidants with potential antiatherogenicity[62].

Antidiabetic

Administration of Myrtus extract significantly reduced the hyperglycaemia induced by streptozotocin. This effect was maintained by its repeated administration. The extract had no effect on the blood glucose level of normal mice. These studies confirm the folk-medicine indication of Myrtus extract as potentially useful in the treatment of diabetes mellitus[63].

The leaves as well as the volatile oil obtained from the leaves are used to lower the blood glucose level in type-2 diabetic patients. Myrtle oil exerts hypoglycaemic as well as mild hypotriglyceridemic activity in diabetic animals[64].

Myrtle oil exerts its hypoglycemic activity by enhanced glycolysis, glycogenesis and decreased glycogenenolysis. Data suggested myrtle oil treatment reduces intestinal absorption of glucose, hence myrtle oil could be a -glycosidase enzyme inhibitor which had a hypoglycemic effect only on alloxan induced diabetic rabbits on the fourth hour and on orally glucose loaded group[65].

Phenolic compounds, extracted from the leaves of M. communis were investigated for the anti-diabetic activity in streptozotocin induced diabetic rats. Biochemical estimations namely serum glucose, cholesterol, triglycerides, HDL, LDL, AST, ALT, BUN, creatinine, total proteins, albumin and globulin were carried out. The studies suggested that phenolic compounds when administered in the dose of 800 mg/kg body weight could produce a remarkable antihyperglycaemic effect than administered at 400 mg[66].

Antimutagenic

Antimutagenic activity of the essential oil of myrtle was studied by collecting the plant samples from the two distant localities and they were

assayed against spontaneous and t-BOOH-induced mutagenesis in Escherichia coli oxyR mutant IC202, a bacterial strain deficient in removing ROS. When the oxidative mutagen was used, essential oil expressed higher reduction of mutagenesis in a concentration dependent manner[61].

Antimutagenic activity of myricetin-3-o-galactoside and myricetin-3-o-rhamnoside, isolated from the leaves of M. communis was assessed using the SOS chromotest and the Comet assay. Both the compounds induced an inhibitory activity against nifuroxazide, aflatoxin-B1 and H2O2 induced mutagenicity; they modulated the expression patterns of cellular genes involved in oxidative stress, in DNA damaging repair and in apoptosis[67].

Induction of apoptosis in cancer cells M. communis is reported to induce cell death of different cancer cell lines with characteristics of apoptosis, visualized by the activation of caspase-3, -8 and -9, cleavage of poly (ADP-ribose) polymerase (PARP), release of nucleosomes into the cytosol, and DNA fragmentation. It caused loss of the mitochondrial membrane potential in MM6 cells and evoked release of cytochrome c from mitochondria[68].

Cardiovascular activity

The aqueous extract of leaves showed a negative inotropic effect in guinea pig and atropine did not block this effect. The total extract caused concentration dependent depressive effect in anaesthetized rabbit which was not attenuated with propranolol, cimetidine and atropine but blocked by theophylline. These results suggest the presence of adenosine like compound in this extract as studied by Al-Zohyri et al[69].

Activity against recurrent aphthous stomatitis A study was conducted to evaluate the clinical efficacy of a novel paste containing M. communis in the treatment of recurrent aphthous stomatitis. The study was a randomized, double-blind, controlled before–after clinical trial. This study showed myrtle to be effective in decreasing the size of ulcers, pain severity and the level of erythema and exudation, and improving the quality of life in patients who suffer from recurrent aphthous stomatitis[70].

Activity against hepatic ischemia

The effect of myrtle on a model of hepatic ischemia-reperfusion in rat was evaluated. To evaluate the effect of myrtle on ischemia-reperfusion, transaminases levels and the concentration of monoethylglycinexylidide were determined. The testing of myrtle extracts in this model of hepatic ischemia showed a significant effect against damage of ischemia-reperfusion[71].

Antiulcer

The study was conducted to investigate the protective effect of the dried berries of myrtle in gastric ulcer against ethanol, indomethacin and pyloric ligation induced models in Wistar rats. Two doses of aqueous extracts and methanolic extracts were administered orally to animals prior to the exposure of ulcerogens. The parameters taken to assess anti-ulcer activity were ulcer index, gastric juice volume, gastric pH, total acidity, gastric wall mucus and histopathological studies. Both the doses of aqueous and methanolic extracts showed significant gastroprotective effects[72].

Narcotic analgesic activity

A screening program of the narcotic analgesic activity of aqueous extract of M. communis was carried out. The myrtle extract exhibited significant narcotic analgesic activity[73].

Adverse reactions and contraindications No health hazards or side effects are known with the proper administration of designated therapeutic dosages. In rare cases, internal administration of myrtle oil as a drug leads to nausea, vomiting and diarrhoea. Preparations containing volatile oil should not be applied to the faces of infants or small children because of the possibility of triggering glottal spasm, asthma like attacks or even respiratory failure. Overdoses of myrtle oil (more than 10 g) can lead to life threatening poisoning, due to high

cineole content. Symptoms include decrease in or loss of blood pressure, circulatory disorders, collapse and respiratory failure[74].

Conclusion

From the time immemorial, plants have been used extensively as curative agents for a variety of ailments. Extensive literature survey revealed that M. communis has a long history of traditional use for wide range of diseases. Many of the traditional uses have been validated by scientific research. A number of phytochemicals isolated from various plants like flavonoids, coumarins, tannins, terpenoids, glycosides, alkaloids, essential oil, etc. have shown a variety of pharmacological activities like anti-diarrhoeal, antiulcer, antidiabetic, antihypertensive, antioxidant, antimicrobial, antimutagenic, etc. in various clinical and pharmacological trials. In recent years, emphasis of research has been on utilizing the vast treasure of traditional medicines that have a long and proven history of treating various ailments. In this regard, further studies are required to be carried out on M. communis for its potential in preventing and treating different diseases.

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Acknowledgement: *Reproduced from Indian Journal of Natural Products and Resources, Vol. 2(4), December 2011, pp. 395-402, We wish to acknowledge with thanks the Editor, Dr. (Mrs.) Sunita Garg for permitting us to reproduce the same.*

I AM A PHARMACIST…..WHY?

By

Ms Divya – Final Year B. Pharm

Vels College of Pharmacy, Chennai.

Almost every tribe of people needs me to be there for them. As long as human race live in this universe, drugs has to exist. Drug plays a role right from the formation of foetal cell as a single ovum in mother's womb till the men goes under the earth. Human race have been pushed to condition that 'no life without drug'. And I say "no drugs without me, a pharmacist".

In ancient days, physicians thought that germs were cause for diseases and cut opened the veins in affected part to squeeze out the blood to remove germs. Many died due to such cruelty. After pharmacist aroused, drugs to eradicate these germs are emerged out.

In ancient days, RISHI compounded and dispensed the medication. In later days, compounder was regarded to compound & dispense. But it is not so.

Pharmacists like me were God fathers for drugs; to give birth to it. Am I boasting on me? No; that's the reality.

Let me say why I'm pharmacist and what I'm to this world.

I'M HERE AS A PHARMACIST TO BRING OUT THE DRUG:

In **R&D,** I discover therapeutically active entity and design it into a final preparation (I'm an innovator). I work on unmet needs in medication field. I check for its potency, pharmacokinetic (ADME) and pharmacodynamic activity and bioavailability. I develop the drug to reach the right target at right time based on chronopharmacology.

As **toxicologist & pharmacologist,** I perform clinical trial and check for safety, efficacy & toxicity of the drug. If I was not there, therapeutic failure due to low dose or toxicity due to over dose will occur. I fix the dose on OECD guidelines and safeguard the people from toxicity (I'm a Safeguardian).

I **manufacture** the drugs into various suitable dosage form Such that particular volume of drug contain particular amount of active ingredient (I'm a Producer). I make the universe to astonish on me by giving out newer drug like liposomal drugs, nano drugs etc.,

Like a swan, I separate good from bad (I'm an Analyzer). The raw material, as well as manufactured product is **analyzed** for its quality and quantity; not only drug but also food. The drug content, stability, shelf life, purity, adulterants, physical and chemical property during transport, storage & in various climates are determined. Through this, I indirectly help the patient to consume the uncontaminated drug before losing its activity.

Only after I assure, every drug and food can enter the market based on FDA guideline. I **pack** the drugs in suitable container based upon its chemical and physical property.

Am I torch light to society? Yes. I bring out the manufactured product to the light (I'm a Marketeer). Doctors and patients come to know about the drug only after I market the product. As a medical rep, wholesaler or retailer, I make the drug available to the patient easily.

I add credit to our country by holding intellectual property for my product and make others not to own mine.

DOES my duty stops here? No. I continue further.

I'M A PHARMACIST, THE HEALTH PROVIDER:

In hospital, I'm here to access medical records, patient compliance, ADR, side effects, therapeutic response (I'm a Supervisor). So that I review the drug activity and facilitate the physician in prescribing drugs without medication error (I'm a backbone).

I counsel the patients about their therapy, when, where & which drug to take, drug & food interaction and conditions to be followed during drug therapy and enhance their MORALE (I'm a Counselor)..

As a part in hospital (PTC) and government (IPA), I give idea about dose regimen, drug selection, ADR and preparation of formulary to shape out health care professionals to fit to current affair (I'm a Shaper).

The record has stated that there occurred 3% to 10% drug related morbidity and mortality of ambulatory patient due to lack of community pharmacists(care taker). Pharmacists like me avoid such medication error.

I'm here to dispense and compound the drug correctly and accordingly to prescription though many do not understand prescriber's writing. I maintain OTC and automatic stop order drugs and dispense it without error.

I'M HERE AS A PHARMACIST IN SURVEILLANCE OF MEDICATION:

As clinical trial is short term process, some drugs show adverse effect slower. So Safety monitoring is done even after performing it to proceed with ongoing effectiveness of drug. Drug like warfarin which caused GI bleeeding was banned because of me to protect the people.

I'M HERE AS AN EDUCATOR (KNOWLEDGE IMPARTER): I'm here to teach pharmacy students, medical student, nursing students.

I also conduct awareness program to make health care professionals and public to be aware on availability of drug therapy. As 'Prevention is better than cure', I setup free camps for public to prevent them from diseases.

I serve as a drug information source (I'm a readily available mobile source).

I'M IN NEW DRUG DISCOVERY:

Now tulasi plant and cockroach was found to possess radio-protecting action. Research was going on to

enhance it in modern therapeutic way to help men in defense forces of nation.

Auto injectors to deliver right dose at target site, detecting kit to detect disease on our own, carbon nano tubes were some of discoveries contributed.

I'M AS A PHARMACIST IN SPACE MEDICINE:

The change in microgravity and fluid distribution, loss of bone density, loss of muscle mass, balance disorders, sleep disturbances, cardiovascular changes, and immune system depression are the various changes in astronauts in space. Thus they undergo many problems. As a pharmacist, here I'm to medicating them in such conditions.

I'M AS A PHARMACIST, THE CITIZEN OF INDIA:

It,s my duty to bring out our India as healthy country (I'm a zealot).

BIOWAR is an emerging warfare to threat nations by culprits with **BIOWEAPONS** (micro organism) like anthrax inducing Anthrax bacillus, botulinium toxin producing Clostridium botulinium, virus inducing small pox.

In 2001, 5 Americans were killed by anthrax letters and many were infected. But it was controlled completely by vaccinations and preventive measures. Pharmacist like me play major role in biowar.

Pharmacists like me are working hard to give out novel drugs for newly emerging diseases like swine flu and also for life threatening AIDS and cancer to save our nation.

CONCLUSION:

Did you got it why I'm pharmacist? "I'm A to Z, an Advisor to Zealot". If not me, then who? No one can replace. I decreased mortality rate in country from 8.88 to 7.48/1000 (2000-2011) through my contribution. I'm a pharmacist and proud to do so. Let Pharmacist like me take privilege to be an unnoticed hero. Soon we will be familiar heroes of the society.

NOTE: The above article is an extract of the Essay competition on the subject of **"I am a Pharmacist…. Why?"** which was awarded Second Prize by TNPSWT.

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 20th November, 2012

G.S.R. 228(E). - Whereas the Central Government is of the opinion that circumstances have arisen which render it necessary to make the rules without consulting the Drugs Technical Advisory Board;

And whereas the Central Government proposes to consult the Drugs Technical Advisory Board within six months of making these rules;

Now, therefore, the following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make 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 Sections 12 and 33 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 shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

Any person interested in making any objections or suggestions on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi - 110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2012.

   (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, hereinafter referred to as said rules, (i), in rule 65,

   (a) in condition (3), in clause (1), in sub-clause (f) and in sub-clause (ii) of the proviso, for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted.

   (b) in condition (9), in clause (a) and (b), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted.

   (c) in condition (11), for the words and letter 'Schedule H', the words and letter "Schedule H and Schedule H1" shall be substituted.

   (d) in condition (11A), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted.

   (ii) in rule 97, in sub-rule (1), after the clause (d) the following shall be inserted, namely:

   (e) if it contains a drug substance specified in Schedule H1, the drug formulations shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on

the left top corner of the label, and shall also be lebelled with the following words in a box with a red border:

'Schedule H1 drug-warning

-it is dangerous to take this preparation except in accordance with the medical advice.

-Not to be sold by retail without the prescription of a Registered Medical Practitioner"

3. In Schedule H, to the said rules, the following entries shall be omitted:

1. "Alparazolam
2. Amikacin
3. Antibiotics
4. Aztreonam
5. Buprenorphine
6. Cefadroxil
7. Cefazolin
8. Cefdinir
9. Ceftazidime
10. Ceftizomixe
11. Cefuroxime
12. Chlordiazepoxide
13. Ciprofloxacin
14. Clarithromycin
15. Clindamycin
16. Codeine
17. Dextropropoxyphene
18. Diazepam
19. Diphenoxylate and its salts
20. Ethambutol
21. Gatifloxacin
22. Isepamicin
23. Levofloxacin
24. Linezolid
25. Meropenam
26. Midazolam
27. Minocycline
28. Moxifloxacin
29. Nalidixic acid
30. Nitrazepam
31. Norfloxacin
32. Ofloxacin
33. Pentazocine
34. Pyrazinamide
35. Sparfloxacin
36. Tramadol hydrochloride
37. Tobramycin
38. Cotrimoxazole
39. Zolpidem"

4. After Schedule H, the following Schedule shall be inserted, namely:

"Schedule H1

(See Rules 65 and 97)

1. Alprazolam
2. Amikacin
3. Amoxicillin
4. Ampicillin
5. Azithromycin
6. Aztreonam
7. Balofloxacin
8. Buprenorphine
9. Carbencillin
10. Cefaclor

11. Cefadroxil
12. Cefalexin
13. Cefazolin
14. Cefdinir
15. Cefditoren
16. Cefepime
17. Cefetamet
18. Cefixime
19. Cefoperazone
20. Cefotaxime
21. Cefpirome
22. Cefpodoxime
23. Cefprozil
24. Ceftazidime
25. Ceftibuten
26. Ceftizoxime
27. Ceftriaxone
28. Cefuroxime
29. Cephaloridine
30. Chloramphenicol
31. Chlodiazepoxide
32. Ciprofloxacin
33. Clarithromycin
34. Clindamycin
35. Cloxacillin
36. Codeine
37. Colistin
38. Dextroropoxyphene
39. Diazepam
40. Dicloxacillin
41. Diphenoxylate
42. Doripenem
43. Ertapenem
44. Erythromycin
45. Ethambutol
46. Feropenem
47. Framycetin
48. Gatifloxacin
49. Gemifloxacin
50. Gebtamicin
51. Imipene,
52. Isepamicin
53. Isoniazid
54. Kanamycin
55. Levofloxacin
56. Lincomycin
57. Linezolid
58. Lomefloxacin
59. Meropenem
60. Midazolam
61. Minocycline
62. Moxifloxacin
63. Nalidixic acid
64. Neomycin
65. Nitrazepam
66. Nitrofurantoin
67. Norfloxacin
68. Ofloxacin
69. Oxacillin
70. Oxytetracycline
71. Paromomycin
72. Pefloxacin
73. Penicillin
74. Pentazocine
75. Piperacillin
76. Polymyxin B

77. Propoxyphene
78. Prulifloxacin
79. Pyrazinamide
80. Rifampicin
81. Sparfloxacin
82. Streptomycin
83. Teicoplanin
84. Tetracycline
85. Tigecycline
86. Tobramycin
87. Tramadol
88. Trimethoprim and Sulfamethoxazole
89. Vancomycin
90. Zolpidem
91. Any other antibiotics

Note: Preparation containing the above drug substances and their salts excluding those intended for topical or external use (except ophthalmic and ear/nose preparations) containing above substances are also covered by this Schedule".

[F.No.X-11014/6/2010-DFQC]

ARUN K. PANDA, Jt. Secy.

Food note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1), dated 21st December, 1945 and last emended vide notification number G.S.R.76(E), dated the 8the February, 2012.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

CORRIGENDUM

New Delhi, the 30th March, 2012

G.S.R. 270(E). - In the notification of Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. G.S.R.426(E), dated 19th May, 2010 published in Part II, Section 3, Sub-section (i) at pages 1-22 of the Gazette of India, Extraordinary and read with the corrigendum G.S.R. 733(E), dated 29th September, 2011 at page 12, sub-rule (2) of rule 1, shall read as follows,

"(2) They shall come into force with effect from 1st day of October 2012"

[F.No. X-11014/4/2006-DFQC]

Dr. ARUN K. PANDA, Jt. Secy.

Foot Note: The principal rule were published in the Gazette of India vide Notification No. F.28-10/45-H (I), dated 21st December, 1945 and last amended vide notification number G.S.R.76(E), dated 8-2-2012.

INFORMATION

M. Pharm Scholarship 2011-2012 awarded by TNPSWT

Profile of 2nd Rank Projects

PHARMACEUTICS

Name: Mr. A. Sampath

Project Title: Formulation and Evaluation of QuetiapineFumarate loaded carbopol 974P Mucoadhesive microspheres for treatment of Schizophrenia

College: Adhiparasakthi College of Pharmacy, Melmaruvathur.

Guide's Name:
Dr.S. Shanmugam., M.Pharm., Ph.D.,

PHARMACEUTICAL CHEMISTRY

Name: Ms. Swati Yadav

Project Title: Synthesis, and anti – Parkinson activity of some novel azetidinone/ thiazolidinone derivatives

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name: Prof. Mrs. Gomathy

PHARMACEUTICAL ANALYSIS

Name: J.Krishna Kiran Gupta

Project Title: Evaluation of Matrix Effects In Bioestimation of Selected Pharmaceuticals By Liquid Chromatography-Mass Spectrometry (LC-MS)

College: Sri Ramakrishna Institute of Para Medical Sciences ,Coimbatore

Guide's Name: Prof. Dr.M Gandhimathi

PHARMACOGNOSY

Name: Ms. S.Padma Thanga Parameswari
Project Title: "Pharmacognosy including Phytopharmacy & Phytomedicine"

College: Madurai Medical College, Madurai

Guide's Name:
Mr.T. Venkatarathinakumar,(Ph.D)

PHARMACY PRACTICE

Name: Mr. Kumaran.N

Project Title: Childhood Nephrotic Syndrome And Steroid Responsiveness – A Single Center Study In ,South India.

College: K.M. College of Pharmacy, Madurai

Guide's Name: Mr. K. Thirupathy

PHARMACOLOGY

Name: Mr. Ankit Sen

Project Title: Temozolomide Niosomes against C6 Glioma cells induced Cerebral Tumors: An in-vitro and in-vivo study.

College: J. S. S. College of Pharmacy, Ooty.

Guide's Name:
Dr. M.N. Satish Kumar M.Pharm., Ph.D.,

EVENTS

Adhiparasakthi College of Pharmacy, Melmaruvathur

One day ACP-Alumni sponsored National Level Seminar on "Recent Trends in Pharmaceutical Research" was held at Adhiparasakthi College of Pharmacy, Melmaruvathur on 31st March 2012. Dr. (Mrs.) N.Girija, Professor, Department of Pharmaceutical Chemistry, Mother Theresa Post Graduate Research Institute of Health Sciences, Puducherry inaugurated the function, Dr. T. Vetrichelvan, Principal, Adhiparasakthi College of Pharmacy gave a talk on the Pharmaceutical education and explained about research activities to the students. He highlighted the need of Pharma education, dedication and discipline among the students to realize their dreams of life. During the inaugural function the top rank holders of undergraduate and post graduate were honored by Trustees by means of issuing Rs.5000/- each and merit certificate.

Periyar College of Pharmaceutical Sciences, Trichy

Guest lecture was organised on cerebral palsy on 07.03.12 to the UG & PG students. During this year Pulse polio programme was conducted on 19.02.2012 to 15.04.2012.

Sri Ramachandra University, Porur

The Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Sri Ramachandra University, Porur, Chennai, organized two days workshop on **"Molecular Docking Studies in Drug discovery"** on 23rd & 24th Feb 2012. Dr. D Chamundeeswari, Principal, Faculty of Pharmacy, welcomed the gathering at the inaugural session. Prof. Dr. S. P. Thiyagarajan, Pro- Chancellor (Research), Sri Ramachandra University, delivered the keynote address, and Dr. K. Chitra, Vice Principal, Faculty of Pharmacy, Sri Ramachandra University, highlighted the on theme **"Application of software in target based drug discovery & its future scope".** Dr. C. Uma Maheswara Reddy, Professor,Dept. of Pharmacology, Faculty of Pharmacy, delivered the vote of thanks. The scientific sessions were conducted by eminent speakers, Dr. Mukesh Doble, Professor, IIT, Chennai, Dr. D. Velmurugan, Professor, University of Madras and hands on training on CHEMSKETCH by the skilled experts of the department. The second day of the workshop started with the plenary lecture by Mr. R. Raghu, Executive Director, Schrodinger (Inc), USA. About 45 delegates from different institutes, including faculty attended the workshop & were trained on the usage of the software related to Docking studies & 3D QSAR by Dr. Ravikumar, Application Scientist, Schrodinger, Bangalore. Dr. K. Sujatha, Professor, Faculty of Pharmacy, proposed the vote of thanks.

Trainers Training Program for Pharmacy Staff and Students on March 14-16th 2012 at Vels University

School of Pharmaceutical Sciences, Vels University and Indian Association of Colleges of Pharmacy jointly organized 3 days "Trainers Training Program for Pharm.D staff and students" on **"Inaugural Quality Pharmacy Practice Module - Advanced Learning Series" on 14th - 16th march 2012 at Vels University. Dr. Ishari K.Ganesh,** Chancellor, Vels University inaugurated the function with Lighting the Kuthuvilaku and delivered the presidential address. Dr. P.Govindarajan, Registrar, Vels University delivered the key note address. Dr.K.Chinnaswamy President, Indian Association of Colleges of Pharmacy, Chennai addressed the gathering. Felicitation Address was given by Archna Mudgal, Registrar, Pharmacy Council of India. New Delhi. **Prof. Krishna kumar,** Howard University, USA delivered the module on therapeutic drug monitoring on first day. **Prof. Dr. Paul Oesterman,** Associate Professor, Pharmacy Practice, Roseman University, USA presented his module on medication therapy management principles and the third day program conducted by **Prof. Dr.Youness R. Karodeh,** Associate Professor, School of Pharmacy, Howard University, Wahington, D.C.USA with his module on diabetes. Dr. S.K.Rajan, Former Dean, Stanley medical College, Prof. M.D.Karvekar., Executive council Member, Pharmacy council of India, Dr.T.K.Ravi, Member of Pharmacy Council of India, Principal, SRIPMS, Coimbatore, Dr.B.Jayakar, Principal, Vinayaka Mission's College of Pharmacy also participated in the event. Dr. R.Mathialagan COE, Vels University participated in the program and other college principals, staff, students also attended the inaugural session. The students got valuable training from the speakers. 96 staff and students of 17 institutions participated in the module.

The program was organized by Dr.V.Ravichandiran, Director, and local organizing committee Dr. J.Anbu, Dr.K.F.H.Nazeer Ahamed, Dr. S. Sathishkumar, Dr. M. Vijayanandhi, Dr.P.Shanmugasundaram and Mr.Senthilkumar, School of Pharmaceutical sciences, Vels University with guidance of valued person Dr. B. Suresh, President, Pharmacy council of India, New Delhi.

NEWS

Pfizer Scouts for Indian Oncology Partners

Pfizer, the research-based pharma company, will invest heavily into oncology research and is looking for Indian companies who could partner with the pharmaceutical giant in treating cancer patients, a senior Pfizer research head said. The company has identified oncology as the therapeutic segment for research in the emerging markets such as China and India since cancer is one of the key causes of premature deaths.

Dr Richard Cornell, vice-president, Asia Research, Pfizer, said: "Oncology is where there is a massive medical need and there is a significant breakthrough in science. Indian companies are very strong in bio-chemistry and so we are looking for partners here." However, he refused to specify how much they would invest in oncology research. The company recently got the approval for Xalkori, a lung-cancer drug that may help the New York-based company to offset $11 billion in possible revenue loss, because of generic copies of the best-selling Lipitor cholesterol pill. According to IMS data, since 2003, Pfizer has increased its number of oncology R&D projects by 400% and dedicated more than 20% of its overall budget to oncology. The company has more than 200 ongoing or planned, sponsored, oncology clinical studies. Pfizer, unlike many Big Pharma companies is not moving away from primary care or metabolic segments. It will continue to focus on both primary care and speciality care segments for developing new products.

Globally, pharma companies are making a paradigm shift in terms of R&D and their outlook towards emerging markets. In terms of research, they are allocating more of their money in the speciality segments such as oncology and focusing on growing in countries with higher population in the East Asia.

Source: *The Economic Times, 18th February 2012*

Natco Gets Licence to Make Bayer's Cancer Drug Copy

Patent controller grants India's maiden compulsory licence

The government has allowed a local drug maker to make and sell a patented cancer drug at a fraction of the price charged by Germany's Bayer, setting a precedent for more such efforts by Indian firms and heightening the global pharmaceutical industry's anxiety over the use of the controversial compulsory licensing provision. The outgoing patent controller of India, P H Kurian, on Monday granted the country's first-ever compulsory licence to Hyderabad-based Natco Pharma, permitting it to manufacture and market a generic version of Nexavar, a medicine used for treating liver and kidney cancer, in India for just 3% of the patented drug's price in return for paying 6% royalty on sales to Bayer.

While healthcare activists were quick to welcome the order and said it would discourage innovator companies from selling medicines at exorbitant prices, Bayer and OPPI, the body that represents foreign drug companies in India, expressed their disappointment at the development. "The solution to helping patients with innovative medicines does not lie in breaking patents," said OPPI Director General Tapan Ray. Bayer is expected to legally challenge the order. "We will evaluate our options to further defend our intellectual property rights in India," a company spokesman said. The order may encourage other Indian drug makers to file for compulsory licences, setting the stage for a spate of regulatory disputes between Indian and foreign drug makers over pricing and patent issues. "The patent controller has ruled that if a product is not manufactured in India after three years of

receiving a patent, it will be a candidate for compulsory licensing. This can have huge consequences as most patented products sold in India are imported," said DG Shah, secretary general of the Indian Pharmaceutical Alliance. Since 2007, at least 18 patented HIV and cancer drugs have been launched in the country.

The compulsory licensing provision arms the government with the power to ensure that medicines are available to patients at affordable rates and has so far been used in Brazil, Thailand and South Africa. It gives the government the right to allow a generic drug maker to sell copycat versions of patented drugs under certain conditions, without the consent of the patent owner. Multinational drug companies had demanded strong safeguards against the liberal use of the provision when India's patent law was being framed, but the final legislation had kept the grounds for invoking this provision open-ended. In his order, the patent controller said Natco's application met three key conditions for granting compulsory licences.

Source: *The Economic Times, 13th March 2012*

National Pharma Pricing Policy May be Dropped

DoP to continue with production cost-based model for pricing of essential drugs.

The department of pharmaceuticals has decided to abandon its controversial "industry-friendly" proposal to cap retail prices of essential medicines at the average price of the three best-selling brands and stick with the cost of production as the parameter.

"The thinking of the department, evolved after considering stakeholders' feedback, is to drop the market-based pricing model and go for the cost-based mechanism," a senior chemicals and fertilizers ministry official told ET.

The department, under the chemicals and fertilizers ministry, has last October sought views on its draft National Pharmaceutical Pricing Policy that proposes to cap the prices of 348 essential medicines and their formulations at the average price of the three best- selling brands.

While the industry had welcomed the draft, others had objected saying it would lead to a rise in prices because the top three brands would usually be the more expensive ones that are most aggressively marketed.

The health ministry, health experts, consumer bodies and the NGO that successfully moved the Supreme Court to force the government to regulate prices of all essential drugs had all derided the proposal. The department's views will now be submitted to the group of ministers headed by agriculture minister Sharad Pawar which is meeting on March 28 to take a final call on the issue.

While the department's view is not binding on the inter-ministerial group, it is expected to be an important consideration while framing the final policy.

The prime minister's office, which has often resolved policy disputes, has however been in favour of the market-based pricing mechanism.

The department's decision is a setback to the industry, especially the bigger players that have been lobbying for an end to cost-based pricing with a top-upto cover marketing costs and profits.

"It is a product of licence raj and has lost its relevance today", industry body Indian Pharmaceutical Alliance said in a recent representation to the health ministry.

An industry executive, who did not wish to be

named, said about half of the 74 drugs under price control are no longer manufactured by companies as they are not profitable. The cost-based mechanism encourages companies to adopt unethical means to inflate cost of production to increase profitability, the executive added.

The health ministry, while maintaining that the cost-based model was ideal, acknowledged that it could be cumbersome and non-transparent.

"But we cannot have a drug pricing policy that cannot reduce the cost of medicines," a health ministry official dealing with the pricing policy said.

Source : *The Economic Times, 22nd March 2012*

Drug Approvals Fall on Account of Tardy & Tedious Process by NDAC

Confusion sparked by the setting up of a new committee for drug approvals has led to a slide in the number of new medicines getting cleared even as millions of Indians struggle with diabetes and heart failures remain a major killer.

The Drug Controller General of India (DCGI) has shed its role as the sole approver of new drugs in the country after a new committee, set up by the health ministry, has taken over crucial approvals.

The New Drug Advisory Committee (NDAC), in turn, oversees the work of 12 committees whose responsibility is to review the files submitted by the industry and give approvals within six weeks. The NDAC has a final say in giving an approval to the drug or rejecting it.

Data from the DCGI shows that the number of new drug approvals dropped to 98 in 2011 from about 224 in 2010. So far this year, the NDAC has approved nine drugs.

"DCGI has become a defunct body as it has no powers in decision-making," said one industry official, who did not wish to be quoted due to sensitivity of the matter. Dara Patel, chairman, Indian Drugs Manufacturers Association, says that there should have been more industry representation.

GN Singh, head, DCGI, did not respond to an e-mail query and phone calls of ET. His office said he is not authorised to speak in the matter.

All this is happening at a time when lifestyle and infectious diseases are affecting a large number of Indians every year. The 5th edition of the Diabetes Atlas shows that about 61.3 million Indians suffer from diabetes while the World Health Organisation estimates that cardiovascular diseases will be the largest cause of death and disability in India by 2020.

Companies say NDAC has made the regulatory process tedious and long. Companies also allege the NDAC has not been sticking to its deadline of giving decision within six weeks and when the committees meet, the approval is outright rejected without giving the firms a chance of re-examination.

The DCGI came under severe criticism last year for issuing licences to companies who were carrying out unethical clinical trials. The matter reached Parliament where questions were raised about the health ministry's role in protecting trial patients. The incidents rattled the health ministry to which DCGI reports.

The drug controller after these allegations in 2010 decided not to take any responsibility of issuing licences.

Post this incident, the health ministry decided to create NDAC that would oversee the matters of drug approvals. Drug companies say DCGI has washed its hands off from drug approvals due to this quasi-regulatory body.

Earlier, for a drug to get approval, companies would directly approach the drug controller's office, who would then consult experts before giving its decision.

Source : *Economic Times, April 20, 2012*

Expat Scientist-entrepreneurs are Relocating to India to Offer Cost-effective Healthcare Innovations

Global scientists of Indian-origin, who have made path-breaking discoveries in the field of healthcare, are moving to India to test, validate and market their innovations. Their aim is to provide handy, affordable solutions for the diagnosis and treatment of life-threatening diseases like cancer. Shiladitya Sengupta and his team, who developed technology to help in cancer treatment at Harvard-MIT division of the Health Sciences and Technology in Boston, have founded a start up - Invictus Oncology - in India.

The Delhi-based start-up is developing nanomedicine - or a drug smaller than one-thousandth the diameter of human hair - which hones in on tumours and reduces side-effects. It shrinks tumours by cutting off blood supply to it and continues to sit on the tumour till it dies.

Sengupta is one among the many new generation scientists who are putting their research to meaningful use and building affordable, low-cost products in India. "I was told that this is a crazy idea as nobody discovers drugs in India, especially for cancer," says Sengupta, whose team aims to develop a drug from India that can be used globally.

Start-ups such as this hope to tap the healthcare market in India, which is expected to swell five-fold and touch $280 billion in 10 years. Some of these cuttingedge technology entrepreneurs spoke to The Economic Times on the sidelines of EmTech India, a technology conference, organised by MIT's Technology Review.

AchiraLabs

Dhananjaya Dendukuri and Suri Venkatachalam are the founders of Achira Labs, a two-year-old medical diagnostic start-up, which has developed a proprietary lab-on-chip platform that can perform a number of tests, including those for thyroid, diabetes and infertility.

The company's chip platform is designed to deliver diagnostic results within minutes of testing, allowing rural patients to receive immediate medical care without having to wait for days or weeks.

"Not having access to diagnostic facilities has been the bane of India's rural population. Our focus is, if you can't come to us, we will come to you," says Dendukuri, a 34-year-old, Ph.D. holder from the Massachusetts Institute of Technology. Achira will kick-start the pilot manufacturing process of its chip this year, with full-scale manufacturing expected to start in 2013. The team is also in the process of developing a fabric-based testing platform, using silk yarn to create an integrated fabric chip.

Dendukuri believes that silk weaving can not only be used to build a low-cost, scalable platform for chip manufacture but can also create employment for the weavers. Funded by the Nadathur Group, Achira Labs has also received a grant of $1 million from Grand Challenges Canada last year. The funding will be utilised to further develop the fabric-based chip to make medical diagnostic tests.

InvictusOncology&VyomeBiosciences

Shiladitya Sengupta, an assistant professor at Harvard Medical School's Brigham And Women's Hospital in the US, has cofounded three life

sciences start-ups in India. Among them are Delhi-based firms Invictus Oncology and Vyome Biosciences.

Invictus is developing nextgeneration anti-cancer drugs. The technology initially developed in Sengupta's lab at Harvard has been further developed by a group of scientists who have relocated to India. Among them are Monideepa Roy, who was teaching at Harvard Medical School, Dipankar Pramanik of Johns Hopkins, and Sajid Hussain of University of California. Sengupta says similar drugs in the US cost $9000 per dose and Indians cannot afford those nano-medicines.

His other start-up Vyome Biosciences, which addresses skin diseases, was started in late 2010 by him and Rajesh Gokhale of Delhi-based Institute of Genomics & Integrative Biology. The company has already filed patents both in India and the US. It has received seed funding from Navam Capital.

JaiMedica

Sanjay Kakkar is the founder of this personalised healthcare venture that has developed a simple saliva-based test to determine how prone a person is to a heart attack or coronary heart disease (CHD) risk. The country's first ever genetic test to check the risk of heart disease is important at a time when India is witnessing an epidemic of CHD, with three million deaths per year and approximately 12% of the population affected annually.

Kakkar, an alumnus of Harvard University and King's College, University of London, was born and raised in the UK. After stints at big drug-makers Novartis and Pfizer, he built and managed Trigen, a UK-based biotechnology company. He led it, from starting off as a spin-out from a research institute into a free-standing business, until it was acquired. Then he relocated to India.

MitraBiotech

It's all about the correct diagnoses, according to Pradip Majumder, chief scientific officer and a co-founder of Mitra Biotech, a Bangalore-based bio-technology company engaged in developing personalised cancer therapy.

Founded in 2008 by a team of Harvard and MIT researchers, Mitra has developed a technology that allows doctors to predict which drugs might work and which won't for a cancer patient, based on the characteristics the tumour.

This also spares patients on whom the drugs might not work from their toxic side-effects. In parallel, Mitra is accumulating a database of 'market-sets' or types of patients whose tumours respond to specific drug combinations. A study has found that nearly six lakh Indians die of cancer every year, with 70% of these deaths between the ages of 30-69 years.

Mitra has already established linkages with the Mazumder-Shaw Cancer Centre and Healthcare Global Enterprises. Separately, the company is also partnering pharmaceutical companies to bring down the cost of cancer treatment drugs and improve their drug development. The company is backed by global venture capital firm Accel Partners, Karnataka Information Technology Venture Capital Fund and India Innovation Fund.

StrandLifesciences

Vijay Chandru is the co-founder and chief executive of Bangalore-based bioinformatics firm Strand Life Sciences. His firm's latest innovation is a virtual liver - a predictive method that integrates data and insights for deeper understanding of the impact of a drug on the liver. The platform can predict toxicity of several known drugs and toxins.

Sengupta of Invictus Oncology says there is a great need for India to develop a network where academic institutions, industrial partners and catalyst funds can partner to take the innovations to market. "Being a scientist is not about just doing bench research but translating research into practice," he says

Source : *Economic Times, April 13, 2012*

Kerala DC Seizes 20,000 Bottles of Cough Syrup for Violation of 18 C of D&C Act from Kozhikodu

Following a tip off from Andhra Pradesh DCA, the officials of the Kerala drugs control department have seized 20,000 bottles of a cough syrup worth Rs.25 lakh from the premises of a wholesale dealer at Kozhikodu, for violation of 18 C of the Drugs & Cosmetics Act (D&C Act).

The large consignment of the drug, Cofcare Syrup, was kept in the godown of the wholesale dealer, Medi Fort, located at Puthiyara in Kozhikodu district. The syrup was manufactured by a company in Andhra Pradesh which had not obtained valid drug licence for its manufacture, sources said.

The seized Syrup contains codeine phosphate IP 40 mg and Chlorphenaramine Maleate IP 40 mg and was manufactured in violation of Drugs & Cosmetics Act by S K Healthcare Formulations based in Ranga Reddy district of Andhra Pradesh, said CS Satheesh Kumar, drugs controller, Kerala.

The company, SK Healthcare Formulations did not obtain valid drug licence to manufacture Cofcare Syrup, said M Kodandaraman, director of drugs control, Andhra Pradesh. He said investigations are going on in Andhra Pradesh also.

The seized products were produced before the chief judicial magistrate court at Kozhikodu and actions are being taken to cancel the licence of the dealer, said S Sreekumar, ADC, Kozhikodu. He said case of violation of 18 C of the D&C Act was taken against the company and the dealer. According to him Medi Fort had purchased the drugs from a stockist, Chemsol Labs Pvt Ltd based at Ameerpet in Hyderabad, Bill No 200 dated February 3, 2012.

The inspecting officers found three batches of the syrup were stocked in the store room of Medi Fort and the MRP printed on the label of the bottle was Rs.75. The officials said the wholesale dealer was previously purchasing the Syrup from Ambika Medicare in Mehsana. They added that the dealer had once bought some quantities of the drug from Kiran Multitrade Pvt Ltd in Patna.

ADC at Kozhikodu told Pharmabiz that the wholesale dealer was selling the drug to traders and hospitals throughout Kerala as a product of Cipla, whose labels were pasted on the bottles. But he said Medi Fort claimed that they had not placed an order for 20000 bottles of Cofcare Syrup with Chemsole Labs and kept the stock in quarantine pending return to the dealer in Hyderabad. More investigations are on, he added.

The officials said a coordinator for sale activities of the drug, one Dr Reghuveer in Tamil Nadu has informed the officials in Kerala that Medi Fort had placed an order for 10000 bottles with Chemsol Labs, but expecting more sales in the coming months in Kerala, the company sent 20000 bottles. Based on this information, the Kerala drugs control department has requested their counterparts in Tamil Nadu to conduct investigation on the sale of this syrup. The regulatory officials in Kozhikodu have frozen the sale of the drugs following the seizure.

Source : *Pharmabiz.com, April 24, 2012*

PCI to Conduct Awareness Programme on Pharm D Course in Central States: Dr B Suresh

Pharmacy Council of India (PCI) will introduce a slew of measures to create awareness on Pharm D programme among faculties and students in the pharmacy colleges in north India. As a first step in this regard, a workshop will be conducted in June in Raipur in Chhattisgarh, said Dr B Suresh, president, Pharmacy Council of India.

The president of PCI was responding to a news item appeared in Pharmabiz on April 12 which said that pharmacy colleges in the central India, especially in Chhattisgarh, were averse to Pharm D programme as the managements and faculties were feeling that the programme was not at all suitable for Indian scenario.

He said, apart from infrastructure facilities, lack of means and resources to comply with the specified preconditions in the rules and regulations for starting the program may be the major reason for the colleges in Chhattisgarh and in Madhya Pradesh to stand indisposed towards the six year doctorate in pharmacy course. The mandatory conditions for starting the Pharm D program elucidate that the college should be approved under section 12 of the Pharmacy Act for conduct of B. Pharm programme. It should have tied up with a 300 bed general hospital. The faculties of the college should include minimum two teachers with pharmacy practice qualification. Besides, the hospital facility should contain a space of at least 1000 sq.ft inside.

To the comment by a college principal in Chhattisgarh that the program is not adequate to manage a clinical pharmacy in the western countries, Dr Suresh replied that the programme was designed by involving experts from India and abroad, and the needs of India and of global expectations were considered while the curriculum was framed.

"We are continuously receiving feedback on the curriculum and the council has appointed a committee to look into all these aspects and suggest changes and modifications if any. The first batch of Pharm D will be passing out in 2013 and we are looking at amendments if any to be incorporated then", he said.

Agreeing that there is a need to create awareness about the programme amongst the students and faculties to avoid all sorts of confusions, he maintained that PCI would do all efforts towards clarifying every ambiguity. So, PCI is planning to organize an awareness programme in June in Raipur, and is ready to address any kind of difficulty faced by students at the institutional level or university level, Dr Suresh pointed out.

Regarding shortage of facilities for industrial training for students in the central Indian states, the president commented that the institutions and universities should plan industry-academia interactions to strengthen its activity. PCI and IPA are always supportive to any move by the state governments towards attracting industry into the states, he said adding that the northern part of India is always industry oriented and the southern side is health oriented.

When asked whether PCI would initiate any action against those colleges and their principals for openly making remarks about Pharm D programme, Dr Suresh said PCI is acting as guardian of the profession, not a regulator. "We are open to receive suggestions, criticisms substantiated with reason and even allegations with proof. It is the voluntary decision of the colleges whether to start the programme or not. It is not being mandated or forced by the PCI on the institutions, the PCI president told Pharmabiz.

Source : *Pharmabiz, , April 25, 2012*

New USP Ref. Std Released & United States Pharmacopeia RS Catalog

Following new USP Reference Standards were released recently.

Catalog #	Description
1011732	Adapalene Related Compound C (25 mg) (2-(adamant-1-yl)methoxybenzene)
1011743	Adapalene Related Compound D (25 mg) (4,4'-dimethoxy-3,3'-di(adamant-1-yl)biphenyl)
1011754	Adapalene Related Compound E (25 mg) (2,2'-binaphthyl-6,6'-dicarboxylic acid)
1042634	Aripiprazole (200 mg)
1042656	Aripiprazole Related Compound C (25 mg) (1-(2,3-dichlorophenyl)piperazine hydrochloride)
1042689	Aripiprazole Related Compound F (25 mg) (4-(2,3-dichlorophenyl)-1-[4-(2-oxo-1,2,3,4-tetrahydroquinolin-7-yloxy)butyl]piperazin 1-oxide)
1042690	Aripiprazole Related Compound G (25 mg) (7-{4-[4-(2,3-dichlorophenyl)piperazin-1-yl]butoxy}quinolin-2(1H)-one)
1065480	Beta Carotene (3 x 250 mg) (COLD SHIPMENT REQUIRED)
1097680	Cefepime Related Compound D (20 mg) ((Z)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetic acid)
1097691	Cefepime Related Compound E (20 mg) (1-{[(6R,7R)-7-Amino-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl}-1-methylpyrrolidin-1-ium chloride)
1098504	Celecoxib (200 mg)
1098515	Celecoxib Related Compound A (10 mg) (4-[5-(3-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide)
1098526	Celecoxib Related Compound B (10 mg) (4-[3-(4-methylphenyl)-5-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide)
1152600	Cyclamic Acid (100 mg)
1265800	Ethyl Lauroyl Arginate (200 mg)
1269130	Famciclovir Related Compound E (25 mg) (2-aminopurine)
1269141	Famciclovir Related Compound F (25 mg) (2-Amino-6-chloropurine)
1302258	Native Gymnema Extract (1 g)
1302247	Gymnemagenin (15 mg)
1347664	Irinotecan Related Compound E (15 mg) ((S)-4,11-Diethyl-4-hydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione)
1357486	Latanoprost Related Compound A (50 mg) (Isopropyl (E)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate)
1365065	Levothyroxine Sodium (50 mg)
1458053	Neohesperidine Dihydrochalcone (100 mg)
1483174	Oxcarbazepine Related Compound B (10 mg) (N-Acetyl-10-oxo-10,11-dihydro-5H-dibenzo[b,f]azepine-5-carboxamide)
1483200	Oxcarbazepine Related Compound E (10 mg) (10(11H)-Oxo-5H-dibenz[b,f]azepine)
1510889	Perindopril Erbumine (100 mg)
1510890	Perindopril Related Compound A (20 mg) ((2S,3aS,7aS)-octahydro-1H-indole-2-carboxylic acid)
1543200	Piperine (20 mg)
1578805	Protein A (250 uL/ampule; 2 ampules) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)
1642879	Tadalafil (200 mg)
1712001	Vigabatrin (100 mg)

USP Reference standards catalog can be seen in Ms-Excel format on
http://www.usp.org/sites/default/files/usp_pdf/EN/referenceStandards/usprefstd.xls

USP Reference standards catalog can be seen in pdf format on
http://www.usp.org/sites/default/files/usp_pdf/EN/referenceStandards/dailycatalog.pdf

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Sun Pharmaceutical Industries Gets Favourable US Supreme Court Verdict in Patent Case

Sun Pharmaceutical Industries today said the US Supreme Court has given a favourable verdict in its patent case against Novo Nordisk over generic Prandin tablets used for treating diabetes.

US Supreme Court has ruled in favour of the company's subsidiary, Caraco Pharmaceutical Laboratories, in it's patent litigation against Novo Nordisk over Caraco's generic version of prandin, repaglinide tablets, Sun Pharma said in a statement.

"The Supreme Court, in a unanimous opinion, concluded that Caraco can seek correction of Novo Nordisk's inaccurate use code regarding the combination use of repaglinide and metformin for the treatment of type II diabetes," it added.

The judgement has said, "The text and context of the provision demonstrate that a generic company can employ the counterclaim to challenge a brand's overbroad use code. We accordingly hold that Caraco may bring a counterclaim seeking to 'correct' Novo's use code..."

Prandin is a registered trademark of Denmark-based drug firm Novo Nordisk.

The decision will help all generic companies prevent brand companies from misrepresenting their patents to the USFDA and improperly delaying or preventing generic companies from marketing their drugs, Sun Pharma said.

Caraco's abbreviated new drug application (ANDA) for generic Prandin is still awaiting approval by the United States Food and Drug Administration (USFDA), it added.

"Prandin has annual sales of approximately $ 230 million in the US," Sun Pharma said.

A separate appeal concerning the validity of patents for Prandin is pending before the Court of Appeals for the Federal Circuit after a lower court ruled in favour of Caraco, it added.

Scrips of Sun Pharma were trading at Rs 596.50 apiece in the afternoon on the BSE, up 2.11 per cent from its previous close.

Source : *Economic Times, April 18, 2012*

மருந்தாளுநர்களுக்குப் புத்துணர்வு விழா

திருநின்றவூர் ஜெயா மருந்தியல் கல்லூரியில் மருந்தாளுநர்களுக்கான புத்துணர்வு விழா அண்மையில் நடந்தது.

நிகழ்ச்சிக்கு ஜெயா கல்வி அறக்கட்டளைத் தலைவர் அ. கனகராஜ் தலைமை தாங்கினார். வேல்ஸ் மருந்தியல் கல்லூரி முதல்வர் வி.ரவி சந்திரன், இந்தியன் ஃபார்மசூட்டிக்கல் அசோசியேன் தமிழ்நாடு கிளைச் செயலாளர் ஜே.ஜெயசீலன், தமிழ்நாடு ஃபார்மஸி கௌன்சில் பதிவாளர் டி. இளங்கோ ஆகியோர் சிறப்பு விருந்தினராகக் கலந்து கொண்டனர்.

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NEW REFERENCE BOOK

The following Reference Books have been added to the Tamilnadu Pharmaceutical Sciences Welfare Trust Library.

1. British Pharmacopoeia - 2012

2. I.P. Addendum - 2012

3. Merck Index - 14th Edition

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This issue of Pharma Web is also available online at the Trust website www.pictrust.com

64th INDIAN PHARMACEUTICAL CONGRESS

The IPCA has decided to hold the 64th INDIAN PHARMACEUTICAL CONGRESS at Chennai. The Congress will be held from 7th to 9th Dec 2012. The venue of the Congress will be **SRM University**, Potheri Village at Kattangulathur near Chennai.

The session will be presided by Prof. K. Chinnaswamy. Mr. S. V. Veeramani, Managing Director, Forrts india will be the **Chairman** of the Local Organizing Committee. The other important Office Bearers are:

Local Organizing Secretary - Prof. B. G. Shivananda (APTI)

Associate Organizing Secretary - Mr. J. Jayaseelan, Secretary, IPA, TN Branch

Treasurer - Dr. Madhavan (APTI)

Associate Treasurer - Dr. Ravichandran (Vel's College of Pharmacy).

The Tamilnadu Pharmaceutical Sciences Welfare Trust office will be the Local Address of the Congress.

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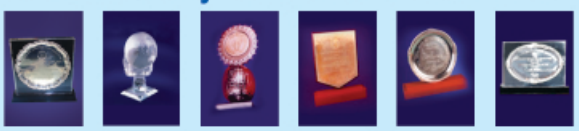

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