



RESÚMENES / ABSTRACTS

CONFERENCIAS PLENARIAS (PL) O CONFERENCIAS (L) / PLENARY LECTURES (PL) OR LECTURES (L) LUNES, 20 DE NOVIEMBRE / MONDAY, NOVEMBER 20

PL01- ETHNOPHARMACOLOGY AND THE SEARCH FOR NOVEL MEDICINES / HEALTH FOODS. ARE WE BARKING UP THE RIGHT TREE?

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Drug discovery from nature and the pharmacology of natural products are areas which share many common methodologies, but the goals of the various approaches often differ considerably. Both areas have been essential for developing today's medicine chests used all over the world (1). It is estimated that 25% of all prescription medicines are derived from natural sources. In the fields of anticancer and anti-infective medicine, this figure is about 80% (2).

A classical approach has been the bio-assay guided search for new chemical entities with specific *in vitro* effects which can then be developed into new drug leads an area I have had a long standing interest. A core pharmacological target used by my group has been the transcription factor NF- κ B an element of the pro-inflammatory signalling cascade (Palladino et al 2003). Importantly, we use a multiple-target approach to identifying molecular sites of inhibition within the inflammatory response (3). For example, crude extracts of *Witheringia solanacea* leaves showed inhibition of NF- κ B activation at 100 μ g/mL induced by phorbol 12-myristate-13-acetate (PMA) in HeLa cells stably transfected with a luciferase reporter gene controlled by the IL-6 promoter. Three physalins were isolated from an active fraction, namely, physalins B (1), F (2), and D (3). Of these compounds, 1 and 2 demonstrated inhibitory activities on PMA-induced NF- κ B activation at 16 and 8 μ M and induced apoptosis after 24 h in a cell-cycle analysis using a human T cell leukemia Jurkat cell line. Compound 2 also inhibited TNF-R-induced NF- κ B activation at 5 μ M through the canonical pathway, but was inactive in the Tet-On-Luc assay, indicating specificity of action, although it interfered with Tet-On-Luc at higher concentrations. It is suggested that the presence of a double bond and an epoxy ring between carbons 5 and 6 in compounds 1 and 2, respectively (which are not present in compound 3), are related to their anti-inflammatory activity. This work using bio-assay-guided fractionation provides molecular evidence that the anti-inflammatory activity of *W. solanacea* and its physalin constituents (1-3) is likely to be mediated via the NF- κ B pathway (4). *While this work provides exciting information about bio-active constituents and their mechanism of action, only a few of such compounds will finally reach the market as new drugs and the costs for developing such molecules is extremely high.*

Thus industry's interest is moving towards means for faster development of new products. One line is based on the development of extracts into herbal medical products or health foods. Specifically in Europe there is an increasing demand for herbal medical products with a concomitant increase in concern about some of the products quality and safety. The European Union recently established a simplified registration procedure for traditional herbal medicinal products for human use (Directive 2004/24/EC), which requires all products to be licensed and offers a novel way of licensing based on traditional use. Traditionally prepared herbal medicinal products are commonly used on a small scale and the control of the product's quality and safety is in the hand of those who use these products. On the other hand commercial products are generally a commodity which is no longer controlled by the users and specific requirements for good production, storage and distribution (GAP, GLP, GMP) are required. Thus these products become a commodity which is regulated to varying degrees in the various countries.

This political framework sets the scene for the changing needs in studying and developing drugs from natural sources. Essentially such products may be (health) foods, herbal unlicensed medicines, or licensed medical products. Over the last years the focus has been on the benefits and risks of drug discovery? Where is the cat then? And, therefore, are we barking up the right tree? In essence our focus has been very much on the discovery of novel entities, but shouldn't we focus more on the development of existing extracts and guaranteeing their quality and safety?



References: 1. Heinrich, M and H.L. Teoh (2004) Galanthamine from snowdrop – the development of a modern drug against Alzheimer's disease from local Caucasian knowledge. *Journal of Ethnopharmacology* 92: 147-162 (doi:10.1016/j.jep.2004.02.012). 2. Newman, D. J., M. Cragg, and K. M. Snader (2003) Natural Products as Sources of New Drugs over the Period 1981-2002 *Journal of Natural Products* 66, 1022-1037. 3. Bremner, P. and M. Heinrich (2005) Natural Products and their role as inhibitors of the pro-inflammatory transcription factor NF- κ B. *Phytochemistry Review* 4 (1): 21-37. 4. Jacobo-Herrera, P.D. Bremner, S. Gibbons M. Gupta, S. Muñoz and M. Heinrich (2006) Physalins from *Withania frutescens* (Solanaceae) as inhibitors of the NF- κ B cascade. *Journal of Natural Products* 69 (3): 328-331 (DOI: 10.1021/np050225t).

PL02- NATURAL AND TRADITIONAL MEDICINE: INTEGRATION TO THE NATIONAL HEALTH SYSTEM IN CUBA

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The Natural and Traditional Medicine (NTM) has been integrated at the Cuban National Health System since 1995. A net along the country has been created for these specialties implementation at every health attention level. Investigations about these therapeutic modalities have allowed us to obtain enough scientific evidences for achieving appropriate use of these procedures. In 2005, 12 006 717 ambulatory patients, 346 315 hospitalized patients and 2 933 302 patients in services of urgency were attended by the use of different therapeutic modalities of Natural and Traditional Medicine. In this period, 74% of surgery and clinic specialties have used the NTM for therapeutic purposes. In such sense, 20 400 000 flasks containing natural medications have been wasted. Over the last 10 years, in our country, an upward development in the systematic utilization of natural therapies has been achieved in the National Health System. On the other hand, to achieve a sustained and growing development of the traditional medicine and their integration to the programs of health, it is essential to carry out pharmacological investigations in this field that allow to evaluate the impact of the alternative traditional therapies in the main indicators of health, aspects these that are part of the main priorities of investigation and development in NTM at this moment showing a sustained growth in the Cuban National Center for Natural and Traditional Medicine.

PL03- ANTIOXIDANT DIETARY FIBERS: A POTENTIAL TOOL FOR PREVENTION OF OXIDATIVE STRESS ASSOCIATED DISEASE

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Dietary fibers with exceptional amounts of natural antioxidants associated with the fiber matrix were obtained from mango, pineapple, guava, seaweeds and grape. These antioxidant dietary fibers (AODF) combine in a single material the physiological effects of both dietary fiber and antioxidants. Studies of their properties are in progress. This communication is mainly focussed in grape AODF. Grape AODF has a high amount of phenolics (16 % dry weight-proanthocyanins, flavonoids, resveratrol and phenolic acids-) with capacity to act as antioxidants in both lipophilic (lipoproteins, cell membranes) and hydrophilic systems (plasma). Several biological tests showed that grape AODF was effective in quenching free radicals, protecting DNA damage and significantly retarded human LDL oxidation. High intestinal antioxidant status and effective hypocholesterolemic effect were observed in rats' experiments. On this basis, different clinical trials – sponsored by the Spanish Ministry of Education and Science- are being conducted at Hospitals (Madrid and Barcelona) to check the potential effects of grape AODF in antioxidant status and in prevention of cardiovascular disease and colorectal cancer. Healthy volunteers received a daily dose of 7.5 g of grape AODF. Preliminary results of these trials will be presented.

References: 1. Saura-Calixto, F. (1998). Antioxidant dietary fiber product: A new concept and a potential food ingredient. *J. Agric. Food Chem.*, 46:4303-4306. 2. Martín-Carrón N., Goñi, I., Larrauri, J.A., García-Alonso, A., and Saura-Calixto, F. (1999). Reduction in serum total and LDL cholesterol concentrations by a dietary fiber and polyphenol-rich grape product in hypercholesterolemic rats. *Nutr. Res.*, 19:1371-1381. 3. Jiménez-Escrig A, Rincón AM, Pulido R, Saura-Calixto F (2001). Guava fruit (*Psidium guajava* L.) as a new source of antioxidant dietary fiber. *Journal of Agricultural and Food Chemistry* 49: 5489-5493. 4. Pulido R., Jimenez-Escrig A.,



Orensanz L., Saura Calixto F. and Jimenez Escrig A. (2005) Study of plasma antioxidant status in Alzheimer's disease. *Eur. J. Neurology* 12, 531-535

PL04- INTERACTIONS BETWEEN HERBAL MEDICINES AND PRESCRIPTION DRUGS

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Monitoring the use of herbal medicinal products (HMPs) is difficult since many are bought from outlets other than pharmacies; assessing the incidence and significance of herb-drug interactions (H-DIs) is therefore even more problematic. There is also widespread under-reporting of adverse reactions to herbal products for many reasons, so the extent of H-DIs is still largely unknown. However the use of HMP's among the general public is increasing, and it has been estimated recently that in the US, 24% of the general population regularly take herbal products. In other parts of the world, especially in developing countries, this is much higher, and at these levels of usage it is very likely that some clinically significant herb-drug interactions will occur.

Many consumers believe herbal medicines to be safe simply because they are natural, and although this is obviously untrue, there is a real concern that exaggeration of safety issues based on purely theoretical grounds will further polarise public opinion. The patient may then ignore even sound advice on the subject, leading to a serious adverse event, so it is important that accurate information is available on this subject.

In this presentation, the theoretical and clinical evidence for some important H-DIs will be presented, together with an explanation of pharmacodynamic interactions and pharmacokinetic effects involving P-glycoprotein and Cytochrome P450 enzymes. An attempt will also be made to put the issue in perspective: for example, it is becoming clear that certain herbal drugs are most frequently cited in interaction reports; these include St John's wort (*Hypericum perforatum*), Dan Shen (*Salvia miltiorrhiza*), Dong Quai (*Angelica sinensis*), Cat's claw (Uña de gato, *Uncaria tomentosa* and *U. guianensis*), ginseng (*Panax* species), goldenseal (*Hydrastis canadensis*), liquorice (*Glycyrrhiza* species) and *Ginkgo biloba*. The main prescription drugs involved are those which are already susceptible to interactions with many others, such as warfarin, digoxin, protease inhibitors, statins and anti-cancer drugs.

CONFERENCIAS PLENARIAS (PL) O CONFERENCIAS (L) / PLENARY LECTURES (PL) OR LECTURES (L) MARTES, 21 DE NOVIEMBRE / TUESDAY, NOVEMBER 21

L01- ETHNOPHARMACOLOGY OF DISEASE PREVENTION FROM ANCIENT ISLAMIC TEXTS

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Traditional texts usually mention medicinal uses of different agents for the treatment of diseases, rather than their prophylactic use for the prevention of diseases. In this report, an attempt is made to present use of different agents mentioned in old Islamic texts for the prevention of disorders. Literature search was carried out of the classical Islamic texts reported from Prophet Muhammad, peace be upon him and his descendents. Over 20 records of prophylactic uses of medicinal plants, honey and salt were found in literature from the Islamic sources. These include medicinal uses for the prevention of forgetfulness, infectious diseases (including leprosy), leucoderma, bad breath, fatigue and laziness, general weakness, depression, colic, hemorrhoids, uncontrolled micturation, facial palsy (Bell's palsy) and general paralysis, maintenance of good health, improvement of memory and cognition, blood purification and fertility. Scientific literature search indicated that in most of the instances, no research is reported on the basis of prophylactic uses mentioned in Islamic texts. I conclude that ethnopharmacologic investigation of prophylactic uses of medicinal agents can be an interesting area of research and its potential must be explored by the scientific community.



L02- DRUG DISCOVERY THROUGH HISTORIC HERBAL TEXTS

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L03- ROLE AND SCOPE OF ETHNOMEDICINAL PLANTS IN THE DEVELOPMENT OF ANTIVIRALS

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Ethnomedicinal plants have been used as source of drugs for almost all diseases, but the number of compounds having antiviral activity is scarce. Irrespective of type of viruses and the cells they infect, there are a very few specific viral targets for the phytomolecules to interact. Most of the available antiviral drugs often lead to the development of viral resistance, side effects, recurrence and viral latency. A wide range of ethnomedicinal plants showed strong antiviral activities and many of them either inhibit replication, or genome synthesis of many viruses. Hence, development of new antivirals of natural origin is an urgent need. This review will cover some of the promising antivirals isolated from ethnomedicinal plants with proven *in vitro* and some documented *in vivo* activities.

L04- *In vitro* ANTIOXIDANT ACTIVITY OF THREE PIPER SPECIES: A COMPARATIVE STUDY

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Introduction: Free radicals, reactive oxygen species (ROS) and reactive nitrogen species (RNS) are implicated in numerous oxidative stress related pathological conditions. Thus substances with antioxidant capacity capable of scavenging free radicals and reactive oxygen species can play a role in oxidative stress related disorders. The polyphenolic content and free radical scavenging activity of methanolic leaves extracts of three *Piper* species (*Piper guineense*, *Piper nigrum*, and *P. umbellatum*) were studied in-vitro. **Materials and Methods:** Folin Ciocalteu method was used to assess the polyphenolic content while the reducing power, 1,1-diphenyl-2-picrylhydrazyl (DPPH), superoxide radical, hydroxyl radical, nitric oxide scavenging and metal chelating activities were employed in studying the radical scavenging activity of extracts. **Results:** All three spices exhibited a marked polyphenolic content and dose dependent free radical scavenging activity. The free polyphenolic content of the three spices was in the order *P. umbellatum* (15.93±1.89 mg/g) > *P. guineense* (12.56 ± 0.25 mg/g) > *P. nigrum* (9.75 ± 0.76). The three *Piper* extracts exhibited a 79.76 – 89.92 % scavenging effect on DPPH, an 85.10 – 97.85 % scavenging effect on nitric oxide at a dose level of 10mg/ml and a 47.07 – 51.60 % scavenging effect on superoxide radical at a dose level of 8mg/ml extraction. *Piper* extracts also exhibited a 56.99 – 76.06 % scavenging effect on hydroxyl radical at 5 mg/ml, a 0.39 - 0.58 reducing power and an 88.33 -93.90 % metal chelating activity at a dose level of 8 mg/ml extraction. **Conclusion:** Thus these *Piper* species contain high antioxidant capacity and can play a role in the modulation of oxidative stress related disorders.



L05- PHARMACOLOGICAL ACTIVITIES AND THERAPEUTIC POTENTIALITY OF NATURAL EXTRACT OBTAIN FROM STEM BARK OF *Mangifera indica* L (VIMANG) AND ITS GLUCOSYLXANTHONE, MANGIFERIN

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The aqueous extract from stem bark of *Mangifera indica* L (VIMANG) has been used in Cuba during several years in ethnomedical practices for the improvement of quality of life of patients with different pathologies¹. A phytochemical characterization of the extract has led to the isolation of nine phenolic constituents, with the glucosylxanthone mangiferin as a major component, and different microelements as zinc, copper, and selenium². The extract has demonstrated as the main pharmacological property its antioxidant activity³⁻⁵. Others studies have shown that the extract also possesses others pharmacological activities, such as: anti-inflammatory⁶⁻⁹, antiallergic¹⁰, analgesic⁶ and immunomodulator¹¹⁻¹², with very complex and multifactorial mechanisms of action involved. These properties are related to its scavenger capacity of different reactive oxygen species. The interaction of mangiferin and others component of the extract with Fe²⁺, represent an important antioxidant mechanism recently characterized in our studies¹³⁻¹⁴. On the other hand, mangiferin and Vimang have the property of modulating different mediators involved into immune response, more specifically: 1) Inhibit nitric oxide and pro-inflammatory cytokine production in several inflammatory conditions, 2) Inhibit phospholipase A2 activity and eicosanoid production, 3) Stimulate TGFbeta production as anti-inflammatory cytokine, 4) Inhibit activation of transcriptional nuclear factor κB (NF-κB)¹⁵, 5) Protect from T cell depletion by Activation-induced cell death (AICD)¹⁶, results that showed these compounds enhance T-cell survival by inhibiting activation-induced T-cell death, a finding associated with a decrease in oxidative stress within the activated T cells. In general, the total extract and its xanthone, mangiferin are involved in several immunomodulatory processes, properties that confer an important therapeutic potentiality as active component for the preparation of phytopharmaceuticals products for the treatment of pathologies where oxidative stress and immunomodulator disorders are related with their etiology. Different clinical studies are conducted at this moment in order to get new knowledge about its therapeutic potentiality.

References: 1. Guevara M et al. *Rev Cubana Farmacia* 36 (Suplem. 2):166-167, 2002. 2. Núñez Selles A. et al. *J Agric Food Chem* 50:762-766, 2002. 3. Martínez G. et al. *Phytother Res* 15:245-2474, 2000. 4. Martínez G. et al. *Pharmacol Res* 42:555-573, 2000. 5. Martínez G. et al. *Free Rad Res* 35:465-473, 2001. 6. Garrido G. et al. *Phytother Res* 15:18-21, 2001. 7. Garrido G. et al. *Pharmacol. Res.* 50:143-149, 2004. 8. Garrido G. et al. *Pharmacol. Res.* 50:165-172, 2004. 9. Garrido G. et al. *Phytomedicine* 13:412-418, 2006. 10. García D. et al. *J Pharm Pharmacol* 58:382-92, 2006. 11. García D. et al. *Int. Immunopharmacol* 2:797-806, 2002. 12. Leiro J. et al. *Int. Immunopharmacol.* 4:991-1003, 2004. 13. Pardo-Andreu GL. et al. *Pharmacol. Res.* 51:427- 435, 2005. 13. Pardo Andreu GL. et al. *Eur. J. Pharmacol.* 513:47-55, 2005. 14. Garrido G. et al. *Phytother. Res.* 19:211-215, 2005. 15. Hernandez P. et al. *Int Immunopharmacol* 6:1496-1505, 2006.



**CONFERENCIAS PLENARIAS (PL) O CONFERENCIAS (L) /
PLENARY LECTURES (PL) OR LECTURES (L)**

MIÉRCOLES, 22 DE NOVIEMBRE / WEDNESDAY, NOVEMBER 22

L06- POSITIVE EFFECTS OF A MULTIVITAMIN-GUARANÁ PREPARATION ON MENTAL PERFORMANCE AND MENTAL FATIGUE DURING A SUSTAINED PERIOD OF MENTAL DEMAND

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The present study tested the effects of a multivitamin-mineral supplement with guaraná (Berocca Boost Performance) on aspects of cognitive performance and self-reported mental fatigue during sustained, effortful mental processing. This double-blind, randomized, placebo-controlled, parallel group study assessed the acute effects of a single dose of either the vitamin/mineral/guaraná supplement or placebo, in the form of an effervescent drink, in 129 healthy young adults (18-24 years). Testing included the Northumbria University Cognitive Demand Battery (CDB) which involves serial completion of a 10-min battery comprising of Serial Threes subtractions (2 min), Serial Sevens subtractions (2 min), and Rapid Visual Information Processing [RVIP] (5 min) followed by a 'Mental Fatigue' visual analogue scale. Salivary caffeine levels were co-monitored. On the testing day, overnight fasted participants attended the laboratory at 9 am. Following two (practice and baseline) pre-dose completions of the CDB participants consumed their treatment. Starting 30 minutes following drink administration, participants made 6 consecutive completions of the battery (60 minutes in total). The most striking finding was a significant improvement, compared with placebo, in both speed and accuracy of RVIP performance associated with the vitamin/mineral/guaraná combination. This effect was evident throughout the hour of testing. The active treatment also significantly reduced ratings of subjective mental fatigue at later, more fatiguing, repetitions of the battery. This research supports previous findings concerning the psychoactive properties of guaraná and provides evidence for the first time in humans that a multivitamin-mineral preparation with guaraná can improve cognitive performance and reduce the mental fatigue associated with sustained mental effort.

L07- THE EFFECTS OF GALANTAMINE ON ATTENTION IN THE DEMENTIAS

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Introduction: Galantamine is an alkaloid obtained from the Caucasian snowdrop and related species. It is a specific and reversible acetylcholinesterase inhibitor registered for the treatment of mild to moderate Alzheimer's Disease (AD). Galantamine also enhances the intrinsic action of acetylcholine on nicotinic receptors. In a comparative parallel group study of galantamine versus donepezil in AD patients, in addition to the expected benefits to memory of both compounds, galantamine produced significant improvements in attention. The effects were seen at 6 weeks and persisted until the end of study at 26 weeks. This suggests that the nicotinic action might be particularly beneficial for attention. Dementia with Lewy Bodies (DLB) is characterised by attentional deficits and fluctuations, therefore a suitable target for treatment with galantamine. **Materials and methods:** An open label, 24-week study to evaluate the efficacy of galantamine for the treatment of DLB in 49 patients over 50 years old. The Cognitive Drug Research computerised assessment system was used to measure aspects of episodic memory, working memory and attention at weeks 0 (training), 4 (baseline), 12 and 24; parallel forms were administered to prevent learning effects. **Results:** The intention-to-treat analysis showed significant improvements to Power of Attention and Coefficient of Variance at week 12 ($p < 0.05$). Statistical signals were identified for Continuity of Attention at week 24, and Quality of Episodic Memory at weeks 12 and 24 ($p < 0.1$). The results showed early benefits of treatment, particularly to measures of



attention and fluctuations, key features of DLB. **Conclusions:** The nicotinic action of galantamine appears to have beneficial effects on attention in demented populations. Such benefits may not be detected with standard clinical assessments (ADAS-Cog) which focus primarily on memory. However, comprehensive computerised assessments of cognition can be useful in identifying the beneficial effects of plant-derived compounds and elucidating the mechanisms by which they occur.

L08- PHYTO-THERAPEUTICAL APPROACHES TO ALZHEIMER'S DISEASE

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One of the most disabling features of the aging process and in certain neurodegenerative diseases is cognitive dysfunction, particularly loss of memory (dementia). Dementia is a chronic, progressive neurodegenerative disorder with characteristic deterioration of intellectual capacity in various domains: learning and memory, language abilities, reading and writing, praxis and interaction with the environment. Alzheimer's disease (AD), the most common type of dementia, is a major cause of morbidity and mortality, accounting for 50-60% of dementia cases in persons over 65 years of age. There are over 15 million people suffering from AD worldwide. The current licensed treatment for AD is based on inhibition of the cholinergic enzyme acetylcholinesterase (AChE) and in some instances also butyrylcholinesterase (BuChE). Drugs in development include those preventing amyloid formation (e.g. beta-secretase inhibition), nicotinic or muscarinic receptor modulation, glutamate receptor antagonism, and both anti-inflammatory and statin activities. Because of the complexity and diversity of the pathological causes of AD, the treatments that will be developed in the future are most likely to be poly-pharmacological in approach. In this respect phyto-therapies, with the multiplicity of chemicals and bioactivities present in an individual plant or combination of plants, provide a novel and relatively unexplored potential.

L09- THE ROLE OF VITAMINS AND MINERALS IN MENTAL PERFORMANCE

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The significant interdependence of nutrition and cognitive functions was recognized many decades ago. Adequate levels of vitamins and minerals are essential for sustained mental performance through physiological processes that have both a direct (e.g. neurotransmitter synthesis, receptor binding, membrane ion pump function) and indirect (e.g. energy metabolism, cerebral blood supply) effect on brain and nerve functions. In this context the minerals calcium, magnesium and zinc and, especially, the water-soluble vitamins (B group and vitamin C) are the most relevant micronutrients. Research indicates that inadequate intake of one or more of these micronutrients is not uncommon even in developed countries and that a large proportion of the population is failing to consume the recommended levels with the normal diet. This situation is being exacerbated in many societies by occupational pressure and a stressful lifestyle leading to the consumption of 'fast food' which has a significant negative relationship with vitamin consumption. This may have consequences for mental performance of the concerned individuals, because it is well established that marginal micronutrient deficiencies result for example in fatigue, anxiety, irritability, sleeplessness and can impair memory and ability to concentrate even in otherwise healthy individuals. Some studies have assessed the effects of a multi-vitamin/mineral product (Berocca®) on self-ratings of stress or psychological well-being. Results following treatment demonstrated a significant benefit of supplementation in terms of improved anxiety/stress ratings across various psychometric parameters. These findings indicate that multivitamin/mineral preparations can help to cope with the negative consequences of stress in individuals at risk of consuming insufficient micronutrients from their diet. In modern societies with the widespread desire for constant optimum performance in all areas of life, vitamin and mineral supplements may therefore help to manage stress and hence to enhance mental performance.



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PLENARY LECTURES (PL) OR LECTURES (L)
JUEVES, 23 DE NOVIEMBRE / THURSDAY, NOVEMBER 23**

L10- CARIBBEAN MARINE BIODIVERSITY

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L11- PEPTIDES OBTAINED FROM MARINE ORGANISMS USEFUL FOR BIOMEDICAL RESEARCH

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Number of marine peptides has been isolated in recent years which exhibit potent biological activities, and many of the compounds showed promising anticancer activity. Didemnin was the first marine peptide that entered in human clinical trials in US for the treatment of cancer, and other anticancer peptides such as kahalalide F, hemiasterlin, soblidotin and aplidine have entered in the clinical trials. Also, there exist known marine toxins waiting for the discovery of pharmaceutically oriented new specificities. Acid-sensing ion channels (ASICs) are Na⁺ channels activated by external protons. These channels are formed by the homo- or heteromeric association of six different subunits. Scientific research in the last years have associated these channels to several pathological and physiological conditions such as pain, learning and memory. For many years, animal venoms have yielded a great number of toxins that modulate specifically and with high affinity voltage-gated Na⁺, K⁺ and Ca²⁺ currents, Ca²⁺-gated K⁺ channels and mechano-sensitive K⁺ channels. To date the pharmacology of ASIC channels is still limited due to the lack of specific modulators, being these of great interest for biomedical application. For this reason, our research was focussed to the isolation and characterization of a new peptide, extracted from a sea anemone acting upon ASIC channels. Also, there exist other compounds, presumably of peptidic nature, that are being evaluated on glutamatergic and cholinergic responses as well as on different voltage activated ionic channels.

L12- CHEMISTRY DIVERSITY OF COMPOUNDS OBTAINED FROM MARINE MACRO ORGANISMS

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Advances in the sophisticated instruments for the isolation and characterization of marine natural products, and development in the biological assay systems, have resulted in the discovery of various compounds of biomedical application from marine origin from which more than 10 are registered as new drugs. Marine products have been a source of new leads for the treatment of many deadly diseases such as cancer, acquired immuno-deficiency syndrome (AIDS) etc. Compounds of marine origin are diverse in structural class from simple linear peptides to complex macrocyclic polyethers. Marine natural products chemists have always shown a great interest in the natural functions of the metabolites that they study. While the interest in obtaining novel chemical structures from microorganisms and plants has declined, the discovery of new chemical compounds with unique structures from marine organisms is increasing. Several of these compounds have been used by population as feed, insecticides,



fragrances, pigments and medicines but the enormous potentiality of the ocean as a source of new compounds is still unexplored. Terrestrial plants have been used for many years as complementary medicine considering the folk knowledge, actually near 25 % of all drugs sold in pharmacies are derived from plants. In the present paper will be presented an up to date review of compounds derived from plants and the studies done in Cuba.

L13- ANTI-INFLAMMATORY, ANALGESIC AND ANTI-OXIDANT OBTAINED FROM MARINE SOURCE: REALITY AND FUTURE

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Marine sources are being explored during more than 40 years, for possible pharmaceutical products. Marine pharmacology has begun to focus on several new areas of pharmaceutical development, with an emphasis, between others, on inflammatory diseases. Inflammation possesses several mechanisms, beginning with phospholipase A₂ activation, prostaglandin or leukotriene formation, reactive oxygen species activity, etc. For these reasons we are going to talk about some of the products that have been obtained from marine organisms, especially algae and sponges, which present anti-inflammatory, analgesic and anti-oxidant properties and their different mechanisms of action. Moreover we will show our most interesting results in extracts obtained from algae, sponges and marine plants which have activity through different mechanisms.

L14- EXTRACTS FROM CARIBBEAN SEAWEEDS AS POTENTIAL ANTITUMOURALS

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The marine organisms have been revealed as an important source of bioactive substances of great value for the treatment of some illnesses for their therapeutic properties (antiviral, anti-inflammatory, antioxidant, as antibiotic, and other). In this paper are presented some results obtained in the chemical and pharmacological evaluation of Caribbean seaweed as a biotechnological source of bioactive substances. Seaweeds (*Chlorophyceae*, *Phaeophyceae* and *Rhodophyceae*) have been processed by different methods as drying and extraction in aqueous, ethanol and non-polar solutions, in cold and hot systems. Also, they have been evaluated as nutraceuticals for their nutritional composition mainly the carbohydrate, antioxidants, neuroactives and anti-tumoural activities through different biochemical assays and in vivo conduct and pharmacological tests with mice and as anti-tumoural (i.e.) in front of the mouse tumour line of leukemia P₃₈₈ transplanted in mice B₂D₆F₁. The chemical characterization of the seaweed and extracts included qualitative and quantitative chemical methods and the fractionation by partition with solvents. Some fractions were isolated and characterized by flash chromatography on Silica gel 60 and analyzed by UV spectra, TLC and HPLC. The results are the basis for the future utilization of the biotechnological properties of the Caribbean seaweeds since they are sources of typical carbohydrates such as carrageenans, agar, fucoidans or alginates and for the secondary metabolites as polyphenols, flavones and terpenes with antioxidants, neuroactives and antitumoural properties detected or as human food as nutraceutical feed. Some of these results have been published and patented in Cuba.



L15- MARINE ORGANISMS AS SOURCES OF NEUROPHARMACOLOGICALLY ACTIVE COMPOUNDS

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Natural compounds obtained from marine organisms have proved to be specific pharmacological tools in Neurobiology. Different taxonomical groups have been used as source of new compounds being sponges, molluscs, Cnidarians and seaweeds the most used. Taking in account the richness of Cuban marine ecosystem our work has the goal to find new tools to investigate on neurobiology at a molecular level, and promising molecules or products potentially used for biomedical applications. In the present work we show some results we have obtained in the neuropharmacological characterization of extracts/compounds obtained from different sea anemones and seaweeds. From different sea anemones we have characterized bioactive peptidic compounds acting specifically on receptors and voltage activated ionic channels. Additionally, we evaluated some neuropharmacological effects of extracts/compounds obtained from different seaweeds combining behavioural and electrophysiological techniques. The results support the interest in continuing the work with at least two of the studied seaweeds.

L16- AGONIST LIGANDS OF NEURAL NACHR IN LOW MOLECULAR WEIGHT FRACTIONS FROM THE TENTACLES EXTRACT OF THE PELAGIC COELENTERATE COLONY *Physalia physalis*

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Nicotinic receptors are pentameric ligand-gated cation channels that are activated by the neurotransmitter acetylcholine. The major brain subtypes seem to be the $\alpha 4\beta 2$ and $\alpha 7$ nAChRs. They are located in presynaptic terminals or extrasynaptic sites, exerting a predominant modulatory action in CNS. A modulatory action offers attractive therapeutic opportunities and that is why the current interest in nicotinic acetylcholine receptors as therapeutic targets for diverse neurological and psychiatric conditions, has led to the development of nicotinic drugs with more subtype selectivity as a major goal of pharmaceutical industry. In this sense, the abundance and diversity of marine organisms as well as their pharmacological potential have led us to search for substances acting on nicotinic acetylcholine receptors subtypes, from the tentacles extract of a coelenterate colony arriving to Cuban seashores between February to March. The extract was prepared for further chromatography separation of active fractions. A purification strategy consisting of gel filtration separations in Sephadex-G50, Sephadex G-25 and HW-40 followed by one reversed-phase step was lined to achieve such purpose. Previous evidences in rodent behavioral experiments suggested the presence of neuroactive cholinergic compounds in the low molecular weight fractions from the first chromatographic steps. After chromatography procedure, three (numbered 1, 2 and 3) very hydrophilic low molecular fractions were tested for their capacity to displace ¹²⁵I bungarotoxin and ³H-cytisine, from $\alpha 7$ y $\alpha 4\beta 2$ receptors from cultured mammal neurons. Experiments based in two-electrode voltage clamping of *Xenopus laevis* oocytes, injected with cDNA coding for neural human $\alpha 7$ and $\alpha 4\beta 2$ receptors subtypes, were carried out to determine the physiological activity. One of these fractions was analyzed by mass spectrometry, which revealed the presence of low molecular weight compounds in the range 200-600 Da. From these results we conclude that in the aqueous extract of the coelenterate analyzed there are very hydrophilic low molecular weight compounds which act as agonists upon $\alpha 7$ and $\alpha 4\beta 2$ subtypes of nACh receptors. A next goal will be to achieve a higher purification degree that allows us the full chemical and pharmacological characterization of such compounds.



L17- COMPOUNDS WITH PHARMACOLOGICAL ACTIVITY OBTAINED FROM MARINE MICRO-ORGANISMS

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Marine biodiversity is extremely high, a direct consequence of the extraordinary variability of the marine biosphere. The potential of marine organisms for commercial development and exploitation impinges on virtually every area of biotechnology. The biological activities of bacterial strains belonging to Marine Microorganisms Collection (Centre of Marine Bioproducts) isolated from the Cuban platform were evaluated. The results evidence the biotechnological potential of these isolates ones since they presented activity against human pathogens considered clinically unsociable, and also versus fish and plant pathogens. Microorganism's potentially producing surfactants, hemolytic and proteolytic activity, antitumour and anti-inflammatory agents were also detected. In another hand the 25 % are capable to the degrade hydrocarbons in different conditions. From several screenings we found isolates having three, four or five biological activities. As many as 57% of the bacteria present in the collection showed wide-spectrum activities.

L18- RESULTS OF THE BIOREMEDIATION STUDIES DEVELOPED AT CEBIMAR AND ITS APPLICATIONS

Núñez-Moreira R, Ortiz E, Oramas J, Fonseca E, Villaverde M, Bellota M, Riverón L, Martínez J, Garcia A, Barbán O, Cabranes Y, Batista C, Miranda A, Paneque K, Díaz Y, Martínez C, Pizarro R

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Bioremediation is based on the idea that organisms are capable to take in things from the environment and use it to enhance their growth and metabolism. With this unique characteristic lay the fundamental principle of Bioremediation, to use microorganism to take in contaminated substances from the environment or convert it to a nontoxic form. Bacteria, Protista, and fungi are well known for degrading complex molecules and transform the product into part of their metabolism. In the Center of Marine Bioproducts (CEBIMAR) we have developed two products against oil pollution, based on in mixed cultures of five marine bacteria, there are patented and called BIOIL and BIOL-FC. This bioproduct was use in different oil spill in Cuban coastal zone like Bay of Matanzas, Bay of Cienfuegos, Bay of Levisa, Varadero Beach and Jibacoa Beach with good results supported by High-Resolution Gas Chromatography. Another hand we demonstrated they capacity of degradation of different fraction of oil, included the asfaltenes. In all cases, the oil removal was higher than 75 % in only 30 days.

L19- COSMETICS OBTAINED FROM THE SEA. A CUBAN EXPERIENCE

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The use of natural substances in cosmetic industry has gone in increase, for this reason they have been investigated and valued the goods of diverse natural compound and in particular that of marine origin with the purpose of obtaining new preservatives with very well defined biological estates. Different extracts of algae are used as preservatives in formulations for the care of skin and hair, these preservatives, mainly polysaccharides and tannins, have been applied as anti-rust, bacteriostatic, wetter and blocking UV. Cuba like a tropical archipelago possesses a great biological diversity in its marine funds that constitutes an important source for these substances. This work approaches to obtain a product named BM21 of a marine plant (patent CU 22931) which was characterized chemically and valued biological and toxicological with perspectives application as a preservative bioactive for cosmetic formulations. BM21 can



eliminate or alleviate the lesions provoked by photo damage, it has anti-rust properties, it is non toxic, and fulfils the microbiological requirements and is stable and maintains its physical-chemical characteristics at least for 12 months. Also, other seaweeds were evaluated and some of them can eliminate or alleviate the lesions provoked by photo damage, having anti-rust properties and being non toxic preparations.

**CONFERENCIAS PLENARIAS (PL) O CONFERENCIAS (L) /
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PL05- THE CUBAN PROGRAM OF MEDICINAL PLANTS OF THE MINISTRY OF HEALTH. A REALITY AND A CHALLENGE FOR THE GROWING DEVELOPMENT OF THE PHARMACOLOGY OF NATURAL PRODUCTS

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In 1987, the Cuban Ministry of Health organized its first Medicinal Plant Research Program. Its main aim was to validate Cuban people most frequently used plants which were obtained with a national ethnomedical survey. At the same time, a national project to develop Pharmacology and Toxicology took place in a close relation to herb and natural products research. Few years later, the national government and health authorities requested an expert group to review the aims and organization of the herb research in order to get herbal drugs to treat health problems and to diminish the lack of drugs which were expected due to the end of Socialism in East Europe and the increased US blockade. Early results were a list having 51 plant/part/uses which were approved by a Health Ministerial Resolution signed on May 5th, 1990 and a publication concerning most used medicinal plants, named *FITOMED*. Other important releases were: national guidelines for drugs and extracts, herb harvest, herb research, and more than 300 results of the research project to give scientific basis to phytotherapy at the national health system. The program has been reviewed and refocused sometimes according to health system requests. Scientific outcomes have been soon introduced to health practice, to medical sciences education, and to people education.

PL06- PHYTOPHARMACEUTICALS: VETERINARY AND HUMAN NOVEL THERAPEUTIC TOOLS

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Introduction: The rich Cuban plant biodiversity offers to Public Health and Veterinary Medicine important therapeutic alternatives. At CENSA research projects focused to obtain natural health products (NHP) represent one of the main goals. The present work shows some of the examples approaching of NHP from tropical plants, *Bromelia pinguin* L., *Rhizophora mangle* L., *Allophylus cominia*. **Material and methods:** Plants were deposited at National Botany Garden for authenticity. *Bromelia pinguin* L. antihelmintic activity was studied in Holstein calves experiments for veterinary purpose. Pulp aqueous extract of mature fruits (100 and 500 mg) were tested. *Rhizophora mangle* L. bark aqueous extract HPLC was analyzed and extract evaluated for antiseptic and wound healing effect in preclinical and clinical trials (GLP, GCP). Toxicity evaluated according to OECD protocols. Formulation Technology processes adapted conveniently for industrial production (GMP). **Results:** *Allophylus cominia* (L.) Sw aqueous and organic extracts, were tested for hypoglycemic effect on diabetic and non-diabetic rat models. *Bromelia pinguin* treated calves showed no eggs in faeces and no adult parasite in the necropsy 72 hours after treatment. *Rhizophora mangle* L. showed 80% polyphenols with a variety of structures of hydrolyzables and condensed tannins. Preclinical and clinical trials showed a strong antiseptic and wound healing effects. Non toxic effects were obtained. A *Rhizophora mangle* formulation for human (CIKRON-H) and veterinary (CIKRON) use was obtained. Industrial production and technology processes conveniently adapted (GMP). *Allophylus cominia* (L.) Sw aqueous extract in reiteration and an organic



extract in simple, oral doses, showed hypoglycemic effect on *in vivo* rat experiments. **Conclusions:** New natural products from tropical plants investigating at CENSA are very promising for human and veterinary health as well. The opportune Intellectual Property Rights strategy (IPRs), based on patents and / or enterprise secret, protecting results from research projects have represented important tools for commercialization. **Acknowledgments:** I wish to express my gratitude to Professor Christopher Brandford-White, IHRP Director, London Metropolitan University, UK and Prof. Alan Harvey, SIDR Director, Strathclyde University, Glasgow for the opportunity offered to collaborate with CENSA staff on natural products research. Thanks are due to The Cuban Minister of Public Health and The Cuban Minister of Higher Education for financial support of the projects.

References: 1. De Armas E. et al (2005). *Current Medical Research and Opinion*, 21(11): 1711-1715. 2. Fernández O. et al (2002). *Fitoterapia* 73, 564-568. 3. Melchor, G. et al (2001). *Fitoterapia* 72, 689-691. 4. Sánchez LM et al (2001). *Journal of Ethnopharmacology* 77, 1-3. 5. Véliz, T. et al (2004) *Revista CENIC Ciencias Biológicas* 35, 71-76. 6. Marrero, E. et al *Fitoterapia*, (2006). June Vol. 77 (4), pp. 313-5.

PL07- SAFETY AND EFFICACY OF COMMONLY USED HERBS, VITAMINS AND SUPPLEMENTS DURING PREGNANCY AND LACTATION – AN EVIDENCE-BASED SYSTEMATIC REVIEW

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Background: There is a lack of basic knowledge on the part of both clinicians and patients as to the indications for use and safety of herbs used during pregnancy and lactation. **Objectives:** To systematically review the literature for evidence on 1) efficacy, 2) safety/harm during pregnancy and lactation, and 3) pharmacology of 60 commonly used herbs, 9 commonly used supplements and 6 commonly used vitamins. **Methods:** We searched 7 electronic databases and compiled data according to the grade of evidence found. **Results:** We found varying levels of evidence on clinical efficacy of herbs, supplements and vitamins for different medical conditions. We found fair level of evidence of harm during pregnancy for barberry, Oregon grape, goldenseal, blue cohosh, parsley, calamus, juniper, pennyroyal and deadly nightshade. We found very good to good levels of evidence of safety for garlic, horsechestnut seed extract, Echinacea, Korean ginseng, ginger, fish oils, *Lactobacillus* sp., St John's wort, vitamins (D, E, K, B6, folic acid). **Conclusions:** A number of herbs show evidence of being effective aids for a number of conditions, however, some safety concerns are important to highlight for women considering the use of certain herbs during pregnancy and lactation.

PL08- CANNABIS: A TRADITIONAL HERBAL MEDICINE BACK INTO THE PHARMACY

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PL09- PRE-MARKET ASSESSMENT OF NATURAL HEALTH PRODUCTS IN CANADA

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In Canada, natural health products are subject to the *Natural Health Products Regulations* under the authority of the Food and Drugs Act. The *Natural Health Product Regulations* which came into force on January 1, 2004 are the result



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of a comprehensive and inclusive consultation process with Canadian consumers, academics, health care practitioners and industry stakeholders, and are a part of the Government's response to the House of Commons Standing Committee on Health's report and 53 recommendations on the regulation of natural health products in Canada. All natural health products require a product licence before they can be sold in Canada. Obtaining a licence will require submitting detailed information on the product to Health Canada, including: medicinal ingredients, source, potency, non-medicinal ingredients and recommended conditions of use (claim, dosage form, duration of use, route of administration, frequency, and cautions and warnings including contra-indication and known adverse reactions). To ensure the product quality, Good manufacturing practices for natural health products must be employed in the manufacture of these products and a detailed specification with respect to identity, purity and quantity of the product should be submitted. The talk will cover the different requirements of evidence required for the pre-market assessments of natural health product in the traditional, non-traditional and compendial streams.

PL10- REGULATORY STATUS OF HERBAL MEDICINES

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In the last decade there has been a global upsurge in the use of traditional medicine and complementary and alternative medicine in both developed and developing countries. This is one of the main reasons for reinforcing the surveillance of the safety, efficacy and quality control of traditional medicine, complementary and alternative medicines.

This work describes important aspects about the art state of the regulatory status of herbal medicines as well as the main requirements for the registering of herbal medicinal products. Besides that, data related with the countries involved in the WHO program for traditional medicine will be showed. Another important aspect is, the importance of clinical trials in order to guarantee the safety quality and efficacy of NHP, the main mistakes in Clinical Trials of natural products are explained. The market and the main challenges are analysed in the investigation of the phytomedicines as well as the tendencies in the growth of this attractive sector.

The strategies for the development of herbal medicinal products are showed as well as some of the interactions between natural and synthetic drugs. The natural health products are considered a very important source for the health.