

NR-P-001

STUDIES ON THE EFFECTS OF DIFFERENT SYRINGES AND PERSONNEL APPLYING RADIOPHARMACEUTICALS IN THE CLINIC ON THE RESIDUEL ACTIVITY

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Introduction

The type of syringes and the volume of the patient doses of radiopharmaceuticals cause high residue radioactivity in the syringes during application to patients. Therefore the investigation of the effects of syringes type and differences in volume and personnel on residue radioactivity and adsorption were aimed.

Materials and Methods

Two types of syringes were chosen and the residue activity left in 0.5 and 1.0 mL syringes after the application of different TcO-4 activities was investigated.

Commercial radiopharmaceuticals were injected to the patients by nurses and technicians. Then, radiopharmacist withdrew these radiopharmaceuticals to the syringes and emptied in-vitro and amounts of residue activity were determined. The change of residue activity was evaluated depending on the syringe, radiopharmaceutical kit and applicant types.

Results

The residue activity reduced by 35- 45 % in the syringes with flat plungers as the decrease in the amount of radioactivity decreased when the volume was doubled but the radioactivity dose remained the same. The highest values were 15- 38 % in syringes with an elastomeric tip on the plunger.

When the injection of radiopharmaceutical kits were examined the residue activities resulting from personnel application reached up to 10- 22 % whereas the application by radiopharmacist reduced this result.

Conclusion

Injection of radiopharmaceuticals needs special care. It is concluded that less care during injection or the preparation of radiopharmaceutical in syringes will cause decrease in the accuracy of the radioactive dose received by the patient and the residue radioactivity in the syringes will cause and increase in the environmental contamination.

NR-P-003

^{99m}Tc-TRASTUZUMAB: A POTENTIAL RADIOPHARMACEUTICAL FOR THE EVALUATION OF THE OVER-EXPRESSION OF HER2 IN TUMORS.

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Trastuzumab (Herceptin®) is a monoclonal antibody produced by recombinant DNA technology that binds specifically to the human epidermal growth factor receptor-2 protein (also known as HER2). A consequence of the amplification of gene HER2 is an increase in the expression of protein HER2 in the surface of the tumour cells, which result in a constitutively active receptor HER2. It has also been verified that Trastuzumab inhibits the proliferation of human tumour cells with over-expression of HER2.

The purpose of this study was to radiolabel Herceptin with ^{99m}Tc by a direct method, as a previous step to develop a therapeutic radiopharmaceutical.

The addition of 2-mercaptoetanol enabled the reduction of the disulphuric binds of the protein, and so obtaining ^{99m}Tc-S. The ^{99m}Tc-Herceptin was then prepared by the addition of 1 mg of Herceptin to 35 mg of HEDP, 3 mg of SnCl₂.2H₂O and 1 mL of ^{99m}TcO₄- (10- 20 mCi), waiting 15 minutes to 37°C. Radiochemical purity was controlled by: a) HPLC with a Protein-Pak SW 300 column and a isocratic program (buffer phosphate 0,01 M, pH 7,0 and flow 1 mL/min; two peaks at 9,9±0,1 and 10,6±0,1 min); b) ITLC-SG with NaCl 0,9% and acetone (Rf ^{99m}Tc-Herceptin = 0,0); c) EtOH:NH₄OH:H₂O (2:1:5) in ITLC-SG previously imbedded with BSA 5% (Rf Herceptin = 0,7-0,9). Purification was carried out by gel filtration in column PD-10 eluted with buffer phosphate 0,01 M, (pH 7,0). Biodistribution studies in normal male mice CD1 and blood and renal clearance in female wistar rats were performed.

The antibody was radiolabelling with radiochemical purity higher than 90%, showing stability for 3h. No uptake at thoracic level was detected. Blood elimination adjusted to a monoexponential model.

It was concluded that ^{99m}Tc-Herceptin could be prepared by direct method with a suitable stability and a biodistribution pattern which enable further studies.

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NR-P-002

RADIOPHARMACY EXPERIENCE IN TURKEY

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Radiopharmacy covers the professional principles and practices of pharmacology and nuclear radiation in the preparation, dispensing and control of radiopharmaceuticals used either in producing scans used for imaging, metabolic and functional studies of internal parts of the body for diagnostic purposes or in the treatment of patients with several diseases.

Radiopharmacy and education activities have started in 1993 officially. In this presentation, the current status of radiopharmacy has been discussed.

NR-P-004

COMPARATIVE STUDIES OF NOREPINEPHRINE OXIDATIVE DEAMINATION IN DIABETIC AND NON-DIABETIC HUMAN BLOOD VESSELS.

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The present work was undertaken to apply the radiochemical methods to the study of oxidative deamination of some neurotransmitters, particularly noradrenaline (NA), in human arteries of both non-diabetic and diabetic individuals in order to know if diabetes could have any influence in monoamines metabolism. We have evaluated the vascular alterations of human diabetic arteries by the quantification of monoamine oxidase (MAO types A and B) and semicarbazide-sensitive aminoxidases (SSAO).

To determine the best enzymatic conditions the method was applied using two incubation temperatures (24°C and 37°C) and also three pH of phosphate buffer (7,2, 7,4 and 7,6). These results directed the enzymatic activity for a incubation temperature of 37°C and pH phosphate buffer to 7,4. The MAO activities were determined using as specific substrates, 3H-5-hydroxytryptamine (32,5 to 1000µM) for MAO A, 14C-β-fenyletylamine (5 to 1600µM) for MAO B and 14C- benzylamine (50 to 1600µM) for SSAO. The Km and Vmax of each enzyme was also determined.

The MAO A in non-diabetic vessels, showed an enhanced affinity and activity when compared with diabetic vessels.

According to the results obtained for MAO B affinity and activity values were similar for diabetic and non-diabetic vessels.

SSAO showed similar affinity for diabetic and non-diabetic vessels and activity appeared to be slightly greater in non-diabetic vessels than in diabetic.

From these results we can admit that arteries of non-diabetic patients mainly contain the isoform MAO A. The oxidative deamination is the same for MAO B in the two vessels and the SSAO activity is slightly greater in non-diabetic vessels. This remarks could be the result of the deteriorated blood vessels walls of diabetic patients.

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NR-P-005

RADIOCHEMICAL DETERMINATION OF CATECHOL-O-METHYLTRANSFERASE ACTIVITY IN BLOOD VESSELS OF DIABETIC RATS.

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Catechol-O-methyltransferase (COMT) is the enzyme responsible for the O-methylation of catecholamines widely distributed in tissues from various mammalian species and with high levels of activity. The hypothesis that the COMT is related to diabetes is based on evidence that there are some changes in catecholamine metabolism in patients who suffer from obesity and diabetes mellitus. The study of COMT activity has been tested with human arteries and it allows obtaining reproductive results.

The aim of the present work is to determine the activity of COMT in vascular tissues of rat without and with diabetes, induced by Streptozotocin (STZ) and related with acute (1 week) and chronic (1 month) effects on hyperglycaemia.

The blood vessels (aorta and cava vein) were obtained from normal and diabetic Wistar rats and were homogenized in phosphate buffer pH 7,4 and the COMT activity was determined by radiochemical method, using 3H- noradrenaline (0.4 to 12.8 μ M) as the substrate in the presence of S-adenosylmethionine (0.5 μ M). The reaction mixture contained MAO inhibitors (Monoamine Oxidase - enzyme responsible for deamination of catecholamines) clorgyline 10⁻⁴ M and (-) - deprenyl 10⁻² M for MAO A and MAO B. Protein concentration was determined by the modified method of Lowry.

The values of Km and Vmax for the substrate were determined by Woolf Hanes method, and were expressed in μ moles/L and pmoles/mg protein/h to Vmax respectively and are in the diabetic vessels smaller in the diabetic tissues.

We also studied the noradrenaline (NA) contents trying to establish a correlation between the noradrenaline and the activity of COMT. The endogenous NA levels have been determined by high pressure liquid chromatography with electrochemical detection (HPLC-EC) and this content are also smaller in the diabetic tissues.

With our results we can conclude that the increase of hyperglycaemia induce a decrease in the activity of COMT and also a decrease in the noradrenaline content.

NR-P-006

99mTc(V) AND 188Re(V) DIMERCAPTOSUCCINIC ACID (DMSA) QUALITY CONTROL: AN EVALUATION OF DIFFERENT SUPPLIERS AND LABELLING CONDITIONS.

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99mTc(V)-DMSA has been widely adopted as the imaging agent of choice, mainly for medullary thyroid carcinoma. Rhenium analogue 188Re(V)-DMSA has also been evaluated for targeted radiotherapy of cancer. After labelling procedure following species were reported: different isomers as anti, syn-endo and syn-exo, but also other species could be detected. Tumour uptake and renal excretion has also been described as very variable, being O2 bubbling an important condition to increase both parameters.

The aim of our study is to assess the species which are obtained from different labelling procedures, quality controls and suppliers.

Commercial kits from different suppliers were used to prepare 99mTc(V)-DMSA (Techi, Tecnuclear, Mallinckrodt). In addition 99mTc(V)-DMSA was prepared from 99mTc(III)-DMSA kit, changing pH to 7,5 - 8,5. 99mTc(V)-DMSA was also exposed to O2 or air during 30 minutes. Besides, 99mTc(V)-DMSA was prepared from raw materials. 188Re(V)-DMSA was obtained as follows: 2 mg of DMSA were dissolved in bicarbonate buffer (0.5 M, pH 9), 0.4 mg SnCl2.2 H2O, pH 2, N2 purged and warmed 30 min at 37°. Radiochemical purity of 99mTc(V)-DMSA was controlled by: a) two HPLC techniques b) Whatman 3MM with NaCl 0,9%, acetone and butanol:acetic acid:water (3:2:3); c) electrophoresis on Whatman 3MM, pH = 3.6, 300v for 1 hour. 188Re(V)-DMSA was controlled in similar conditions.

Eventhough 99mTc(V) - DMSA was prepared with radiochemical purity higher than to 95%, different species were detected by HPLC, according to the supplier. Exposition to O2 or air did not seem to affect peaks distribution. The effect of pH showed that optimal complexation is achieved at 8.5 - 9.0 and the radiochemical purity is increased with the time of reaction.

Quality controls are essential in 99mTc(V) and 188Re(V)-DMSA preparation, in order to differentiate the species which are administered to the patient and predict possible in vivo behaviour.

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PB-P-001

PREVALENCE & GENOTYPING OF HEPATITIS-B VIRUS (HBV) IN HYDERABAD, INDIA

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Two billion people around the world (almost 1 out of 3 persons) have been infected with the hepatitis B virus. Many people recover and get rid of the virus, but 400 million people have been unable to get rid of and remain 'chronic carriers' of the virus. Hepatitis B is common in Asia, Southeast Asia, India, parts of Africa, South America, Eastern Europe, and the Middle East. In the United States there are more than one million Americans who have chronic hepatitis B infections. In the present study a detail prevalence and genotyping of Hepatitis-B Virus have been done to find out the percentage of people affected by the disease and an idea for the need of the latest drugs have been predicted to control the disease.

The serum sample from the patients was analyzed for the viral markers HBsAg, HBeAg, HBcIgM, and HBV DNA. This virus shares a common mode of transmission through parental route. This virus is responsible for both acute and chronic Hepatitis.

The prevalence of HBsAg was observed to be 145 (29%) out of 500 serum samples of patients collected at Center for Liver Research, Hyderabad, by performing PCR, RFLP and DNA sequencing analysis. By this we have established a classified method for HBV genome based on viral surface gene of asymptomatic HBV carriers (ASC). It was observed that 17(84%) of serum samples were genotype D1 where as the remaining shows genotype A. Cultural practices such as tattooing, body piercing etc, are the potential sources of spread of infection.

PB-P-003

BENEFITS OF PHARMACEUTICAL BIOTECHNOLOGY INDUSTRY DEVELOPMENT: SELECTED CASE STUDIES AND LESSONS LEARNED FOR SERBIA AND MONTENEGRO

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The author, graduate of Pharmacy School at Belgrade University and currently completing a Masters degree in Bioscience Enterprise at the University of Cambridge, presents results of his recent original research into benefits of and key success factors for the national and/or regional development of pharmaceutical biotechnology sector. Analysis of two biotechnology sector development case studies - the United States' Massachusetts Biotechnology Corridor and the South African Cape Biotech - led to identification of: (i) key benefits of this type of development, such as boosts to economic growth, innovation, R&D, and entrepreneurialism, pharmaceutical and health discoveries and contributions to health outcomes, and overall society development; and (ii) key success factors for such development, including clear government strategy and regulation including measures to encourage development (e.g., tax incentives, information, cluster development, IP protection), existing scientific and industry base, commercialization infrastructure, access to capital and grants, and ability to attract and retain talent. Lessons learned from this analysis together with an original survey of key experts and stakeholders in the author's home country of Serbia and Montenegro, helped inform a future roadmap for such development in Serbia and Montenegro including the following key steps: creating a tailored and targeted national strategy and sequenced action plan based on the strategy, promoting entrepreneurialism through regulation and education, enabling private-public partnerships and strengthening the local scientific base and talent pool.

PB-P-002

POLYETHYLENE GLYCOL-GRAFTED NANOCAPSULES FOR SUSTAINED PROANGIOGENIC ACTIVITY OF VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF)

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Aims- The sustained delivery of proangiogenic growth factors for therapeutic angiogenesis in diseased tissue is limited by lack of optimal delivery vehicles. We hypothesized that polyethylene glycol(PEG) surface modified poly (lactide) PLA nanocapsules of VEGF would sustain and enhance its proangiogenic effect.

Methods- Nanocapsules were formulated by interfacial polymer deposition following solvent displacement method. PLA-PEG copolymers were used at 20kDa chain length and PEG content (5-20% w/w of total polymer). The prepared formulations were characterized in terms of in vitro parameters- particle size, release rate, percent entrapment and cell culture studies.

Results- PEG-PLA-VEGF nanocapsules exhibited 72% encapsulation efficiency with a loading of about 180ng VEGF per mg of nanoparticles. Release profile demonstrated reduced burst release of 10% of VEGF from surface modified nanocapsules as compared to 35% release in case of non modified nanocapsules. Better sustained effects were observed with higher PEG content (20% w/w of polymer). It further exhibited sustained and nearly complete release over a period of nine weeks in bioactive form. This was also supported by cell culture studies with enhanced endothelial cell proliferation, migration and morphogenesis.

Conclusion- covalently attached PEG on the surface of nanocapsules can be used as an effective delivery system for growth factors to induce therapeutic angiogenesis.

PB-P-004

DEVELOPMENT OF A METHODOLOGY TO MEASURE THE EFFECT OF DIVALENT CATIONS ON THE TRANSPORT OF CALCIUM BY THE PLASMA MEMBRANE CALCIUM PUMP.

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The plasma membrane calcium pump (PMCA) is a fundamental mechanism to remove Ca²⁺ from the cytoplasm of all eukaryotic cells. PMCA, like all members of the superfamily of P-type ATPases catalyze the hydrolysis of ATP. There are four genes encoding mammalian PMCA. The diversity of PMCA is further increased by alternative RNA splicing that generates more than 20 different variants. At the protein and tissue level, the expression of many of these PMCA isoforms has been confirmed by detection with specific antibodies. The main cation transported by PMCA is Ca²⁺, although other divalent cations (C²⁺) also seem to be transported. However reports about C²⁺ transport are rather controversial. We reported here a method to measure the active transport of C²⁺ in inside-out vesicles prepared from human red cell membranes. Volume changes were followed recording the intensity of light scattered by a suspension of these vesicles which express mostly PMCA 4b.

Results obtained by this methodology showed that (a) it is possible to quantify the transport of Ca²⁺ measuring the slope of light intensity as a function of time; (b) the influence of drugs that could be inhibitors and activators of PMCA; (c) the transport of divalent cations like Zn²⁺, Ni²⁺, Ba²⁺, Sr²⁺, Pb²⁺ and (d) the competence among C²⁺ and Ca²⁺. These results show that the method is useful to assay the effect of C²⁺ different from calcium and drugs present in pharmaceutical preparations that are hazardous for human health. With grants of ANPCYT, UBACYT and CONICET.

PB-P-005

POLYETHYLENIMINE-BASED ANTISENSE OLIGODEOXYNUCLEOTIDES OF IL-4 SUPPRESS THE PRODUCTION OF IL-4 IN A MURINE MODEL OF AIRWAY INFLAMMATION

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Purpose. Interleukin-4 (IL-4) plays a crucial role as an inflammatory mediator in allergic asthma via inducing Th2 inflammation, IgE synthesis, and eosinophil. To develop an effective therapeutic agent which specifically inhibits production of IL-4, antisense-oligodeoxynucleotides (AS-ODNs) against murine IL-4 mRNA were generated and complexed with polyethylenimine (PEI) to maximize intracellular delivery.

Methods. AS-ODNs were generated against translation initiation region of murine IL-4 mRNA, and complexed with various concentrations of linear PEI. The efficacy of AS-ODNs/PEI complexes was tested by measuring IL-4 production in D10.G4.1 cell line in vitro and in a murine model of airway inflammation in vivo. The cellular cytotoxicity was tested by XTT incorporation assay, and the physicochemical properties of AS-ODN/PEI complexes were examined using atomic force microscopy (AFM) and DNase I protection assay.

Results. IL-4 AS-ODNs/PEI complexes were spheres with an average diameter of 98 nm and resistant to DNase I-mediated degradation. When compared to naked ODNs, IL-4 AS-ODNs/PEI complexes showed marked inhibition (33 fold increase as compared to naked ODNs) of IL-4 production in D10.G4.1 cells. Furthermore, IL-4 AS-ODNs/PEI complexes were effective in suppressing secretion of IL-4 in the bronchoalveolar lavage (BAL) fluid in an ovalbumin-sensitized murine model of airway inflammation.

Conclusions. These data demonstrate that complexation of IL-4 AS-ODNs with PEI provides a potential therapeutic tool in controlling inflammation associated with allergic asthma, and further presents an opportunity to the development of clinical therapy based on combination of multiple AS-ODNs of cytokines and/or signaling effectors involved in Th2 inflammation and eosinophilia.

PB-P-006

ENCAPSULATION OF DRUGS WITHIN YEAST CELLS ALLOWS INCREASED DELIVERY VIA THE ORAL ROUTE

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Oral drug administration is the most convenient route of drug delivery but drawbacks of administration of drugs via this route include poor adsorption in the gastrointestinal tract, degradation by gastric acidity and degradation by first-pass metabolism in the liver. Encapsulation of drugs can protect the drug from the harsh acidity of the stomach, releasing the drug further down the digestive tract where pH is neutral. Penetration of drugs, especially hydrophilic ones, across intestinal cells is controlled by tight junctions, which exist between cells forming a very effective barrier. Some encapsulation materials can enhance the penetration of drugs by reversibly open epithelial tight junctions, and thus increase drug transport.

Yeast cells can encapsulate and retain essential oils and therefore the aim of the present work was to investigate the ability of heat-killed yeast cells to both encapsulate and increase the permeation of model drugs through a cell monolayer using an intestinal cell culture system of Caco-2 cells. Visualisation of the drug transported across Caco-2 cells was carried out using fluorescent compounds and confocal microscopy in order to investigate the transport pathways. Immunofluorescence microscopy found revealed that the tight junction proteins ZO-1 and occludin were involved in the junction-opening process, also were the secondary messengers PKC and protein tyrosine phosphatase.

PP-P-001

COUGH MEDICINES FOR ACUTE COUGH IN BRAZILIAN MARKET

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Acute cough is a common symptom. Over the counters cough medicines (CM) are widely available in Brazil. The aim of this study is to analyse the CM registered in Brazil. To make the identification of antitussive drugs possible, it was made a research in current literature of pharmacology and therapeutics. To find which antitussive drugs are registered in Brazil, it was made a research at the data base of Brazilian Sanitary Surveillance Agency (ANVISA). The clinical trials were searched in Medline and Cochrane Library. In total, 109 antitussive drugs were identified being used in clinical practice. At ANVISA there were 62 drugs registered, in which 17 (27.4%) were single drugs, 7 (11.3%) 02 drugs' combinations (DC), 14 (22.6%) 03 DC, 12 (19.4%) 4 DC and 12 (19.4%) over 4 DC. Among the DC there were 08 (12.9%) herbal drug/herbal drug, 9 (14.5%) herbal drug/drug and 28 (45.2%) drug/drug. Considering the drugs registered there were 09 generic. The register of same drug by different manufacturers was found to the amount of 10. 2 of them have more than 20 registers without considering the different presentations of the medicine. The anatomical therapeutic chemical classification of the medicines was of 9.7% expectorants, 6.5% mucolytics, 1.6% opium alkaloid and derivatives cough suppressants, 9.7% other cough suppressants, 1.6% opium derivative and expectorant combination and 71% other cough suppressant and expectorants combination. Randomized clinical trials were found for only 3 drugs registered in Brazil: bromexin, dextromethorfan and guaifenesin. None clinical trials were found with DC. Systematic review published by Schroeder & Fahey, 2005 found no good evidence for or against the effectiveness of over the counter CM. The evidence regarding the effectiveness of CM available in Brazilian market is inconclusive. The high number of DC without clinical trials raise concern on their effectiveness and safety once these medicines have been sold without medical prescription

PP-P-002

PROFILE OF ADVERSE DRUG REACTIONS RELATED TO THE USE OF GATIFLOXACIN IDENTIFIED BY INTENSIVE SURVEILLANCE IN AN UNIVERSITY HOSPITAL

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Fourth-generation fluoroquinolones are broad-spectrum antibiotics frequently used to treat a wide variety of infections. Gatifloxacin is one of the newest and the most effective quinolones. This study intended to identify suspected adverse drug reactions (ADR) with gatifloxacin and establish their frequency; to describe the ADR identified and establish a causal relation. The research was an observational cross-sectional study realized from May 2003 to December 2005. The patients in use of gatifloxacin were identified by the drug distribution system of hospital pharmacy. In order to identify the ADR that occurred during hospitalization, we analyzed the medical prescriptions and interurrences reported on medical records. The algorithm of Naranjo was used to establish the imputability of ADRs. W.H.O. categories were used to assess the severity of suspected ADRs. The descriptive statistical analysis was performed using SPSS version 10.0 software. Approximately 6% of 379 patients presented at least one suspect ADR. The most frequently ADR were hypoglycemia (4.3%), cutaneous reactions (13%) and hyperglycemia (39.1%). The ADR was classified as possible (88.2%) and probable (11.8%). The gravity was moderate (41.2%) and mild (58.8%). The ADR identified were notified to the Brazilian Pharmacovigilance System. Related cases of hypoglycemia and hyperglycemia have been published in literature since 2002. These results of intensive surveillance made us aware of the possibility of problems with glucose control in any patient receiving gatifloxacin. We should make health professionals aware of this possibility. Additionally, health professionals must file reports to the pharmacovigilance system when they notice unusual ADR. The knowledge of the profile of ADR is very important to safety use. The intensive surveillance of hospitalized patient helps to know better the ADRs.

PP-P-003

UTILIZATION OF PARENTERAL DRUGS IN PAEDIATRIC UNIT OF AN UNIVERSITY HOSPITAL: AN OBSERVATIONAL STUDY.

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Parenteral drug administration has clinical relevance in paediatric care. However the cost to health care system and the risks related to parenteral therapy should be evaluated. The purpose of this observational cross-sectional study was to analyse the utilization of parenteral drugs in a paediatric unit. The prescriptions issued to all patients of the paediatric unit over a three-week period were analyzed. Patients' age, sex and weight were recorded. From the patients in parenteral therapy, their drugs prescribed were recorded as well as their dosage form, doses, and route of administration. The descriptive statistical analysis was performed using SPSS version 10.0 software. A total of 75 patients were admitted, 56% were male. The age range most frequently was the infants. The length of hospitalization was over 20 days (24%), 6 to 10 days (21.3%) and less than 3 days (17.3%). Parenteral route was used to 56 (74.7%) patients, so 19 (25.3%) used other routes or did not use medicine. Intravenous route was used to 52 (92.99%) patients. The number of parenteral drugs prescribed ranged from 1 to 9 per patient; the average was 5. Overall, 47 different parenteral drugs were prescribed to 34 (60.7%) patients. The average of 5 drugs per patient requires more time of nursing team in activities related with drug administration. The reconstitution, administration, dilution and compatibility of intravenous drugs are important considerations, especially in children receiving multiple drug therapy. The pharmacist should give advice on this considerations to the nursing team. The high number of drug prescribed per patient raise concern about safety. The risks of adverse drug reaction increase with the number of drugs used. The pharmacist should stimulate conversion from parenteral to oral administration because it would not just decrease hospital costs but also, increase safety and improve the patients' quality of life.

PP-P-004

PHARMAECOECONOMIC ANALYSIS OF MEDICAL COST OF TREATING SIDE EFFECTS OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

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Introduction: Gastrointestinal (GI) toxicity associated with non-steroidal anti-inflammatory drugs (NSAIDs) is still an important medical and socio-economic problem. Conventional NSAIDs are more often associated with risk of GI side effects than selective COX-2 inhibitors.

Methods: Data base for pharmacoeconomic analysis of the cost of treatment are based on the medical records of the patients treated at the Clinic of Gastroenterology, at the Military Medical Academy (MMA), who had endoscopically proven GI side effects in the period from 2001-2004. We applied the price list of MMA for 2005. The following data were used: the number of days spent in hospital, all analysis and diagnostic procedures used in treatment, medical therapy, recommended therapy on leaving the hospital. We excluded drugs used for treating the concomitant disease. For the evaluation of the medical costs, a cost-benefit analysis was applied.

Results: 90 patients, out of 580 examined records, had clinically tested side effects due to NSAIDs and 22 patients were advised not to use conventional NSAIDs. All 22 patients used both diclofenac and proton pump inhibitors, which causes the elevation of medical costs. Results of this study showed that the medical costs of treating GI side effects for one patient were 770 \$. Costs of treatment for one patient were nearly the same as for the two-year use of coxibs.

Conclusion: It is better and cheaper for patients, who had proven GI side effects, to use selective COX-2 inhibitors instead conventional NSAIDs.

PP-P-005

A STUDY OF PRESCRIBING PATTERNS AND ERRORS OF ANTIBIOTICS IN A SAUDI HOSPITAL

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Background:

The term 'prescribing patterns' has been used extensively in studies to describe different aspects of the prescribing process. There are no standard definitions or methodologies for prescribing patterns or prescribing errors studies. The incidence of prescribing errors ranges between 0.5% and 18.8%.

Objective:

In this study we will address the prescribing patterns of antibiotics and the incidence of prescribing errors in a tertiary hospital and the potential relationship between them.

Methods:

A prospective study of all prescriptions in a three-month period (June to August 2003) in a tertiary hospital has been analyzed. The hospital provides both primary and secondary levels of care. Criteria used include frequency of selected prescribed drugs, average number of items per prescription, compliance to the hospital formulary, frequency of prescriptions for antibiotics and parenterals, generic prescribing and diagnosis. All prescribing errors were identified and documented. The incidence of prescribing errors was calculated by dividing the number of errors identified by the total number of prescriptions.

Results:

Total number of prescriptions for the three-month study was 24,404. Emergency Room (ER) and primary care have the highest number of prescriptions (37.1%). The average number of items per prescription is 2.1. The most prescribed drugs by primary care (25.3% errors), emergency are antibiotics (28.2%), medicine (3.7), ophthalmology (22.3), gynecology (7.8), and pediatrics (17.8). The prescription errors were 13.6% in primary care and 22.3% in emergency department.

Discussions and conclusions:

Over 24000 prescriptions were included in this study. The incidence of prescribing errors was 18.8% the average number of items per prescription was 2.1. There was a relation between prescribing of antibiotics and prescribing of trade names ($p < 0.01$), compliance to the hospital formulary ($p < .001$), frequency of injection use ($p < 0.001$) and the incidence of medication errors and the average number of items per prescription.

PP-P-006

HERBAL FORMULATIONS PRESCRIPTION ANALYSIS

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Pharmaceutical formulations containing substances of herbal origin are registered as nutrients or medicines on our market in a great number. This analysis is limited only to the solid pharmaceutical formulations containing only substances of herbal origin (the analysis was not performed with the formulations containing vitamins and minerals).

The aim of this work was to determine the range of prescription and sale of these preparations in 'Tefarm' Pharmacy in Tešanj during time period of one year.

Complete monitoring of prescription and sales of herbal medicines was performed using the apothecary computer system. Since different pharmaceutical formulations are available, as well as different packages of the same preparation and instructions for use, single dose was established as one tablet or a capsule.

From the total number of herbal preparations sold, there have been 49,20% preparations for enhancement of cerebral circulation or 42 974 single doses; 22,42% for sedation; 13,40% for stimulating the immune system; 8,47% for enlarged prostate gland treatment; 2,95% for depression treatment; 1,79% for veins and 1,76% for purgation.

Considering the number of herbal preparations sold and possible interactions between them and the other medicines, it is necessary to establish systemic monitoring in herbal medicine prescription in order to avoid side effects caused by inappropriate use.

PP-P-007

QUALITY OF CARDIOVASCULAR DRUG PRESCRIBING IN CROATIA, 2001- 2004

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Objective: The purpose was to investigate the outpatient utilisation of cardiovascular drugs in Croatia, during the 2001-2004 period using the ATC/DDDs methodology and to investigate the relationship between the utilisation of particular drug groups and the number of hospital admissions.

Method: Data on outpatient drug utilization were obtained from Zagreb Municipal Pharmacy to calculate the number of DDD, and DDD per 1000 inhabitants per day (DDD/TID). Drug Utilization 90%(DU90%) method was used on the drug prescribing quality assessment. Data on hospital admissions were collected from the inpatient base kept at Zagreb Institute of Public Health.

Results: Total utilisation of cardiovascular drugs (group C), was between 402.9 DDDs/TID and 406.9 DDDs/TID in Croatia during the 2001-2004 period. Agents acting on the renin-angiotensin system (C09) (121.3 DDDs/TID) and calcium channel blockers (C08) (87.5 DDDs/TID) accounted for more than 50% of drugs used for the treatment of hypertension in 2004. The great increase in the utilization was observed for statins (78.3%). A markedly increasing utilization was recorded for ACE inhibitors in combination with hydrochlorothiazide (HCTZ) (40.5%) and angiotensin II antagonists (278%). Comparison of DU90% segment between 2001 and 2004 revealed pentoxifylline and amiodarone to be absent, whereas cilazapril and ramipril in combination with HCTZ, bisoprolol, valsartan and losartan alone or in combination with HCTZ were added in 2004. On the other hand, DU90% segment still contained doxazosin and propafenone, which had no grounds in therapeutic guidelines. During the period of observation, total rate of hospital admissions for major cardiovascular events decreased by 17.2%.

Conclusion: The outpatient utilization of cardiovascular drugs was high during the 2001-2004 period. The utilization pattern was improved in 2004, showing a decrease in the number of hospital admissions for major cardiovascular events.

PP-P-008

DRUG UTILIZATION IN CROATIA IN 2004

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In Croatia, drug costs account for 15% of health care budget. In 2004, 7.5 prescriptions per insured were issued, with highest consumption recorded in the >65 age groups. According to the By-Law on Data and Reporting on Drug Marketing (Official Gazette 29/05), all corporations and physical persons involved in drug wholesale and retail are obliged to submit annual reports to the National Agency for Drugs and Medicinal Products, categorizing the drugs according to the Anatomical-Therapeutic-Chemical (ATC) classification. Data on outpatient and inpatient were collected and processed by the Zagreb Institute of Public Health. The number of defined daily doses (DDD) and number of DDD/1000 inhabitants/day were calculated from data on the size and number of drug packages. Prescription drugs accounted for 86.96% and over-the-counter (OTC) drugs for 13.04% of total utilization in DDD/1000/day, respectively. Inpatient drug utilization accounted for 3.06% and 5.8% of total drug utilization in DDD/1000/day. Group C drugs showed highest consumption with 250.45 DDD/1000/day. At the secondary level of ATC system, the group of vitamins (A11) had highest consumption, predominated by OTC products, followed by psycholeptics (N05), which was the leading group of prescription drugs with 74.33 DDD/1000/day, with benzodiazepines accounting for 75% of their utilization. Amlodipine showed highest utilization among prescription drugs, and simvastatin according to financial parameters. The highest utilization was recorded in the City of Zagreb, and lowest in the Lika County. In conclusion, drug utilization is too high in Croatia, frequently failing to follow the respective professional guidelines.

PP-P-009

UTILIZATION OF ANTIDIABETIC DRUGS OVER A 5-YEAR PERIOD (2001-2005) IN ZAGREB (CROATIA)

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Objective To describe quantitative and qualitative changes in the utilization of oral antidiabetic drugs (OADs) and insulins between 2001 and 2005.

Method Data on outpatient utilization in Zagreb were collected from Zagreb Pharmacy to calculate the number of defined daily doses per 1000 inhabitants per day (DDD/TID) using the WHO ATC/DDD methodology.

Results Total utilization of drugs used in diabetes decreased from 44.01 to 43.33 DDD/TID. Total utilization of insulins decreased by 4.5% (13.54 DDD/TID in 2004), whereas that of OADs increased by 3.4% (29.79 DDD/TID in 2004). During the 2001-2005 period, sulfonylureas (A10BB) and the biguanide metformin (A10BA02) were most frequently used among OADs, and intermediate-acting combined with fast-acting insulins and analogues (A10AD) in the insulin groups. While in 2001 glibenclamide was the most often prescribed OAD (16.26 DDD/TID), its utilization decreased twice, whereas the utilization of metformin increased twofold in 2005 (6.58 DDD/TID). The utilization of the new agent repaglinide increased more than sixfold. Among insulins, the A10AD group retained the leading place. Human insulin predominated the overall utilization of all insulin groups. The utilization of the insulin aspart increased, whereas bovine and porcine insulins have not been used since 2001.

Conclusions The utilization pattern of OADs and insulins changed during the 2001-2005 period. The predominance of glibenclamide in the OADs utilization in 2001 was shared by glibenclamide and metformin in 2005. The utilization of repaglinide showed significant increase. Among insulins, bovine and porcine insulins disappeared, whereas the utilization of the insulin aspart increased.

PP-P-010

ANALYSIS OF FACTORS ASSOCIATED WITH DRUG-DRUG INTERACTION ON ANGIOTENSIN CONVERTING ENZYME (ACE) INHIBITORS: RESULTS FROM THE NATIONAL AMBULATORY MEDICAL CARE SURVEY, 2003

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Objective: Our goal was to examine the impact of potential drug-drug interactions on Angiotensin Converting Enzyme (ACE) Inhibitors in the U.S. outpatient settings.

Methods: This project applied a secondary data analysis using the 2003 National Ambulatory Medical Care Survey (NAMCS) conducted by the National Center for Health Statistics. A series of descriptive analyses were performed to evaluate the prevalence of potential drug interaction. A multivariate logistic regression was developed to exam how patient and physician characteristics impact the presence of drug interaction. All analyses were used SAS statistical software with 0.05 alpha values.

Results : A total of 25,288 visits to office-based physicians were sampled from the NAMCS in 2003, representing 906.0 million visits in the U.S.. Based on the unweighted sample, ACE inhibitors prescriptions were examined in 734 visits (2.9% of the total visits). Benazepril encountered the highest prevalence rate for the drug interaction (56.7%); following by Ramipril (55.1%), Lisinopril (47.8%), Enalapril (45.7%), and Captopril (45.5%). The results of multivariate logistic regression will be presented by Odds Ratio and 95% confidence interval to identify if any predictor variable is significantly associated with drug interaction.

Conclusion: The study reveals a very high prevalence rate (49.5%) of potential drug interactions with ACE inhibitor agents typically used for hypertension. These drug interactions can lead to morbidity or even mortality if appropriate clinical actions are not taken. From the safety viewpoint, there is the legal duty for physicians to pay greater attention to the choice of drugs, particularly for the patients with polypharmacy status. Consideration of patients' accessibility to pharmacists, the vigilant pharmacy services may attribute more success in monitoring potential drug interactions and making appropriate dosage and therapy adjustment.

PP-P-011

REASONS FOR DROPOUT FROM AN ARTERIAL HYPERTENSION CONTROL PROGRAM AT A GOVERNMENT-RUN HEALTH CENTER IN CAMPO GRANDE, MATO GROSSO DO SUL, BRAZIL

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One of the chief concerns in programs for the control of long-term diseases is the high rate of dropout from treatment. In Brazil, few studies have been conducted on the causes of this behavior and on the profile of noncompliant patients. To identify the reasons for dropout from treatment, as described by noncompliant patients enrolled in a hypertension control program at a health center in Campo Grande, MS, Brazil. A survey was conducted from June to July 2005 with noncompliant patients enrolled in the program and their responses were analyzed. Respondents claimed to have abandoned treatment because of lack of medication, adverse reactions, poor service to patients, and difficulties in transportation to the health center. Some patients declared having continued the treatment by other means (privately paid medical visits, purchase of medication with a previously filled prescription). Others stated not feeling any disease-related discomfort and thus not perceiving the need for treatment. A third group informed having replaced the drug treatment by diets and exercise, succeeding in stabilizing their arterial pressure. Respondents presented three major reasons to justify quitting the hypertension control program. The first one relates to the health center itself (poor service to patients, lack of medication, difficulty in making appointments); other respondents claimed that they do not need the medication, that it has side effects, or that they do not perceive any effects from it. Finally, another group claims to have reached health improvements with physical exercise and diet. Irrespective of the reasons given, patients with hypertension need to be monitored, and one of the strategies available for improving the rates of treatment success is the provision of pharmaceutical care.

PP-P-012

THE RESULTS AND PERSPECTIVES OF THE PHARMACOVIGILANCE PROGRAM OF RIO DE JANEIRO, BRAZIL

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Introduction: The Health Surveillance Center of Rio de Janeiro (CVS-RJ) together with the National School of Public Health have implemented the Pharmacovigilance Program with the objective to monitor adverse drug events, in accordance to the National Adverse Drug Event Monitoring Program coordinated by the National Health Surveillance Agency in collaboration with WHO. **Methods:** Description of the results of the Pharmacovigilance Program-RJ, from September 2005 to March 2006. **Results:** In March 2006, UNIFARJ had received 86 reports, 76% of which were suspect ADRs and 24% suspected pharmaceutical defects. Reports were forwarded by hospitals (79%), industries (19%), community pharmacies (2%). Professionals who notified were pharmacists (79%), physicians (15%) and nurses (6%). Suspect ADRs were mostly observed in patients from 30 to 49 yrs (50%). Eleven percent of suspect ADRs were serious and 3% lethal. Eighty-three percent were classified as probable or possible ADRs. Reactions were mainly related to skin (26%), gastro-intestinal (13%) and general disorders (13%). Anti-infectives were related to 51% of cases. For the Program dissemination, flyers and folders were designed and distributed with information on report procedures. Two issues of the Pharmacovigilance Bulletin were published with the time frame. **Conclusions:** In 2005, the Pharmacovigilance Program of RJ was implemented. From 2006, the major aim is the consolidation of the Program. Main strategies are: broadened dissemination, training courses of staff, commitment of health professionals on the importance of notifying and the strengthening of institutional partnerships.

PP-P-013

PHARMACOECONOMIC STUDY OF ACQUIRING ANTI-HYPERTENSIVE DRUGS IN A METAL WORKS NEAR CAMPINAS THROUGH DATA OBTAINED THROUGH A PBM SYSTEM.

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Hypertension is a disease characterized by a rise in blood pressure and constitutes an elevated risk for cardiovascular diseases. The Pharmacy Benefits Management (PBM) manages benefits of access to drugs by reducing costs and motivating its rational use. The objective of this study is to verify if the PBM system can be used as a tool to supply information on the consumption of anti-hypertensive drugs, their use profile and indirect adherence monitoring. During three months (April, May and June 2005) the drug consumption of a group formed by approximately 2500 employees of a metal works near Campinas was analyzed. This company subsidizes 70% of the cost of drugs to its employees. Of this total, 165 workers (6.6%) used anti-hypertensive drugs where 126 (76.36%) were males and 39 (23.64%) were females, totaling 675 drug cases prescribed. The active ingredients prescribed were as follows: 14.54% was enalapril where 45.7% was generic, 34.3% was similar and 20% were reference. The mean monthly treatment cost taking into account one pill per day was of US \$ 8.56 (\$ 18,50 reais) for the generic, US \$ 10.56 (\$ 22,82 reais) for the similar and US \$ 14.29 (\$ 30,86 reais) for the reference. If only generic enalapril was bought, the treatment cost would be reduced by 27.7% and the reduction would not only be greater because despite the subsidy of the company, 45.7% of the purchased enalapril is already generic. The economy made could be destined for anti-smoking campaigns, motivation of physical activities and others, contributing for improving the control of the disease.

PP-P-015

ANALYSIS OF THE ASSIGNATION OF THE MEDICINES FOR THE CLINICAL PEDIATRICS' NURSING TEAM AND THE POTENTIAL RISK OF DRUGS INTERACTIONS.

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The polypharmacy in pediatrics represents a potential risk for the occurrence of drugs interactions (DIs). The aim of this study was identify potential DIs from the assignation analysis carried through for the nursing team, of medicines prescribed to the pediatrics patients of the Unit of Clinical Pediatrics of a general Universit Hospital (HUB) in Brasilia, Federal District, Brazil. One is about a cross-sectional study, analytical-descriptive, where they had observed 90 lapsings, in months of October of 2005 to February of 2006. Results shows that the biggest frequency of lapsings analyzed were of children between 4 to 11 years (46,6%), male (61%) and hospitalization diagnosis of imperfect osteogenesis (31,5%). The ATC classes more prescribed were nervous system (N) 40,2%, systemic anti-infectious (J) 16,5% and digestive system and metabolism (A) 16,5%. The most used drugs were Dipyron (27,34%), Paracetamol (24,02%) and Dissodic Pamidronate (9%). In the evaluation of assignation quality were found 14 potenciales DIs, higher frequently between aminoglycosides x cephalosporins (14,5%) and cephalosporins x diuretics (14,5%). It was observed that 81% of assignation were carried through for the nurse, frequently in the schedules of 6 hrs (13,1%), 12 hrs (13,5%) and 22 hrs (11,8%). They been found some lapsings with drugs not approved for pediatric use (Captopril, metoclopramide and nifedipine). The concentration of medicines in schedules of service transition and nocturnal period, polypharmacy and the use of drugs not approved in pediatrics, they are factors that could unchain DIs undesirable.

PP-P-014

PRESCRIPTION OF CAPTOPRIL PRECEDING BLOOD PRESSURE ELEVATION IN HOSPITALIZED PATIENTS: A PILOT STUDY.

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Aims: To describe the results of a pilot study of evaluation of prescription of captopril preceding blood pressure elevation in hospitalized patients. Methods: This is a cross-sectional retrospective study, developed in a Brazilian college hospital. A chart-view was done by using a standard form. This pilot study included 50 hospitalized patients during the first semester of 2004 that had at least a prescription of captopril in case their blood pressure overshoot a certain limit. For example: captopril 25 mg if blood pressure was $\geq 160 \times 110$ mmHg. Results: The average age of the patients was $52,1 \pm 18,5$ years old. 30(60%) of the patients were female. The average of days of hospitalization was $21,7 \pm 23,8$. 45 (92%) of the patients were in surgical wards and 5 (8%) in medical clinic wards. Only 24 (48%) patients had hypertension and were under maintained antihypertensive drugs. Captopril was given to only 10 (20%) of the patients. 9(90%) of these patients had hypertension and used captopril through sublingual via. Conclusion: The data of this pilot study show the need of a more rational approach concerning the prescription of antihypertensive drugs in hospitalized patients. More conclusive data will be presented after the conclusion of this study.

PP-P-016

MEDICINE PRESCRIPTION PATTERNS AT THE URCAMP PHARMACEUTICAL ASSISTANCE NUCLEUS - BAGÉ, STATE OF RIO GRANDE DO SUL, BRAZIL

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The herein enclosed study intends to supply information on medicine prescription patterns as supplied by the Pharmaceutical Assistance Nucleus of URCAMP/RS [Southernmost Plains Area University], employing as reference prescription indices recommended by World Health Organization. The present is a descriptive-observational-retrospective study in which all prescriptions issued between the months of January and June 2005. As to the average number of drugs per medical prescription the bottomline achieved is 2.8 which is compatible with literature. Considering that within the network spanned by the SUS (Health Unified Service) all medical prescriptions are mandatorily filled in by generical drug denomination, the 80.4% prescripional results achieved on generical drug denomination were satisfactory. As to prescriptions according to the Basic Listings the bottomline-achieved results of 83.7% point toward a general acceptance of same by health area professionals. As to the free dispensing of medicine, bottomline was 69.7% of all medicine prescribed, which is a cause for great concern under the medical-social viewpoint, as patients might be subjected to therapeutical failure due to product-access hampering. Most-prescribed therapeutical groups were dehypertensives, 17.17%; diuretics, 13.09%; antibiotics, 9.75%, and antiinflammatories, 8.21%. A systemic study of herein-presented indices is needed to monitor medicine-usage interaction with global health-care process and in the way scientific and medical communities interact with health service users in the selection of solutions that will involve pharmacological interventions.

PP-P-017

ANTIMICROBIAL EMPLOYMENT WITHIN FAMILY HEALTH BASIC UNITS FROM BAGÉ, RS [STATE OF RIO GRANDE DO SUL, BRAZIL]

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Abusive, indiscriminate usage of antimicrobial drugs is one of the causes pointed at for the emergence of growing antimicrobial-resistant-level microbial strains. Present day prescription practice characterization as assayed by studies among care dispensers in relation to their prescripional habits belongs among such strategies that are adopted for the management of this public health problem. The herein study aims to study antimicrobial employment within Family Care Basic Units (UBSFs) located in the county of Bagé, Rio Grande do Sul state, Brazil, as well as the quantification of such prescriptions and differences presented between Winter and Summer dosages, plus the most-frequently-prescribed groups of antimicrobials identification, and the assessing of employment-pattern differences among the several evaluated health units. The present is a traversal-descriptive-observational-retrospective study, in which all medical prescriptions issued from the selected UBSFs between the months of July 2005 and January 2006. The present study is also representative as concerns the populations cared by the Family Health Program in the city of Bagé, Rio Grande do Sul state, Brazil. Global antimicrobial prescription prevalence was 14% during Winter months and 11% during Summer months. Among such units that were observed, lowest and highest percentiles found were 7.3% and 17.5% on Winter as well as 7.7% and 20.9% on Summer. Most-often-prescribed antimicrobials in the two assessed periods were amoxicilyn and the sulfamethoxazol-trimetoprin association. Drug employment studies have become nowadays an important rationalization strategy on the use of pharmaceuticals.

PP-P-018

NEW DRUGS OF 2005 AND PUBLIC HEALTH NEEDS

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Background

The pharmaceutical market needs an effective medicines policy to provide drugs to care population diseases, to give access to these drugs, to improve rational use, and to avoid those non essential, unnecessary and dangerous. As a strategy of medicines policy, new drugs launched in market should be analyzed, verifying if they accomplish the above requirements and the public health needs.

Objectives

Identify and characterize all new drugs (New Chemical Entities- NCE) registered, in Brazil, in 2005.

Results

In the study period, 13 new drugs were registered: chlormadinone, bortezomib, otilonium bromide, palonosetron, entecavir, epleronone, fosamprenavir, iloprost, nitazoxanida, cadotril, terizidone, tigecicline and ximelagatran.

These drugs will be used for part of country's population. There are diseases with public health interest like Malaria, Chagas disease, and Leishmaniosis that do not have new drugs introduced for it.

Conclusions

According to our findings, diseases of poor populations have not been treated with new drugs launched in the market.

PP-P-019

SPONTANEOUS ADVERSE DRUG REACTION REPORTING SYSTEM: CONTRIBUTION OF PHARMACISTS TO THE NATIONAL SYSTEM OF PHARMACOVIGILANCE IN BRAZIL

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Background: The National System of Pharmacovigilance, managed by Pharmacovigilance Unit, has faced since its creation a strong difficulty among health professionals, including pharmacists: the lack of tradition in reporting adverse events. Many strategies have been adopted to solve this problem, such as implantation of sentinel hospital and notifying pharmacy projects.

Aims: To describe contribution of pharmacists by evaluating suspected adverse drug reaction (ADR) reports sent by them to the Pharmacovigilance Unit during the year of 2004.

Methods: Only ADR reports sent by pharmacists were assessed. They were evaluated according to reporter institution and professional categories, patient sex and age, and therapeutic classes (ATC classification) corresponding to suspected drugs. Reports related only to medicine's deviation problems or ineffectiveness were excluded.

Results: During 2004 Pharmacovigilance Unit has received 1,890 reports, but only 1,253 (66,30%) were specifically about ADRs. From these, 745 (59,46%) reports were sent mainly by pharmacists, followed by physicians (19,47%). Most of the assessed report forms (85,91%) were sent by sentinel and volunteer hospitals. There were more female than male patients (53,02%). The most frequent patient age ranged from 0 to 10 years old (21,21%). The therapeutic classes frequently present were antibacterials for systemic use (25,80%), analgesics (10,18%), and antimycobacterials (5,68%). Serious ADRs corresponded to 161 reports (21,61%), according to WHO classification; seven patients have deceased.

Conclusions: Pharmacist contribution is significant to the National System of Pharmacovigilance; their reports corresponded to more than 50% of ADR reports in 2004. It is expected an increased number of non-hospital reports after widespread implantation of reporting pharmacy project started in 2005.

PP-P-020

ASSESSMENT OF ADVERSE DRUG REACTION REPORTS RELATED TO PEDIATRIC PATIENTS SENT TO PHARMACOVIGILANCE UNIT, BRAZIL

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Background: Few clinical trials select children as study population during a drug development, so adverse drug reactions (ADRs) related to pediatric patients become a concern to National System of Pharmacovigilance in Brazil. Lack of information about ADRs in children makes ADRs more difficult to be detected and reported by health professionals.

Aims: To describe the suspected adverse drug reactions in pediatric patients sent by spontaneous reporting system to the Pharmacovigilance Unit during the year of 2004.

Methods: Only ADR reports related to patients from 0 to 12 years old were assessed. They were evaluated according to reporter institution and professional categories, patient sex and age, and therapeutic (ATC classification) and system-organ (WHO-ART) classes corresponding to suspected drugs and reported ADRs. Reports without age information were excluded, as well as those related only to medicine's quality deviations or ineffectiveness.

Results: During 2004 the Pharmacovigilance Unit received 1,890 reports, but only 1,253 (66,30%) were specifically about ADRs. From these, only 248 (19,79%) reports related to pediatric patients. Most of the assessed report forms (90,73%) were sent by sentinel hospitals, and the pharmacists were the professional who reported more (72,98%). There were more male than female patients (52,82%). The most frequent patient age ranged from 0 to 1 year old (37,10%). The therapeutic classes frequently present were antibacterials for systemic use (29,58%) and psycholeptics (9,86%). The commonly reported ADRs were skin and appendages disorders (16,83%) and autonomic nervous system disorders (13,63%). Fifty-two (20,97%) reports revealed serious ADRs, according to WHO classification; two patients have deceased.

Conclusions: Assessing ADRs related to children is an important strategy, once Pharmacovigilance systems may monitor adverse events and disseminate information for

QP-P-001

DESIGN AND IMPLEMENTATION OF THE QUALITY CONTROL SYSTEM TO A NATURAL PHARMACEUTICAL PRODUCT

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Developing pharmaceutical products from natural sources pharmacist professionals find new challenges with the purpose of to obtain high quality products, difficult task when these medicines are administered by a route of complex administration that cause that their requirements are similar to those of an injectable one. Due to the high requirements for this type of product, each manufactured lot is put under rigorous controls of quality. The present work approaches the design and implementation of a effective Quality Control System with views to guarantee reliable in the results of quality control of a natural pharmaceutical product, complimenting the validation and the uncertainty determination of all the analytical methods, the elaboration of new Reference Materials for the internal control of these tests, the mechanism to treatment of the results out specifications, the use of the statistical control like tools for the improvement of the system with the execution of control graphics that allow the monitor in the time and the tendency analyses among other essential aspects for the fulfilment of the Good Laboratory Practices following the actual specific ISO Guides. Key words: Natural pharmaceutical product, quality control, analytical method validation, and Reference Material.

QP-P-002

DEVELOPMENT OF AN INTERNAL REFERENCE MATERIAL OF PHOSPHOLIPIDS TO THE QUALITY CONTROL OF A NATURAL LUNG SURFACTANT

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The lung surfactants obtained of natural sources at the moment constitute effective therapeutic options for the treatment of the Neonatal Respiratory Distress Syndrome (NRDS). The biochemical composition of these exogenous surfactants presents rich in phospholipids, reason why in the control of quality of this type of product diverse spectrophotometric and chromatographic analytical methods for the identification, separation and quantification of these compounds are used. The present work approaches the design, obtaining and characterization of a Reference Material (RM) of phospholipids for its use as internal control of the chromatographic tests. Two sources of phospholipids of placenta and lung of a same specie were evaluated as raw material, being selected the second because it presented the components of interest, the one went that showed greater performance, smaller expense of organic solvent, and greater availability to acquire it. Three lots of RM were manufactured by means of the optimization of a flow that guaranteed the reproducibility of the process. The biochemical characterization of these three lots was carried out through of the use of analytical methods previously validated and using a comparison with pure standards of phospholipids from SIGMA shown that they comply with all the required quality indicators for this type of product for analytic uses. Key words: Quality control, phospholipids, Thin Layer Chromatography, and natural lung surfactant.

QP-P-003

VALIDATION OF ERYTHROMYCIN MICROBIOLOGICAL ASSAY - EMPLOYING AN ALTERNATIVE EXPERIMENTAL DESIGN

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The agar diffusion method, widely employed in antibiotic dosage, related the diameter of the inhibition zone with the dose of the substance assayed. It is interesting to adopt experimental planning, what may provide better results and an indication of the assay validity. The symmetric or balanced assays (2 x 2) as well as the ones with interpolation in standard curve (5 x 1) are the main designs used in the dosage of antibiotics. This works aims at proposing an alternative experimental design for erythromycin microbiological assay with the evaluation of the validation parameters of the method referring to linearity, precision and accuracy. The design proposed (3 x 1) used 3 doses of standard and 1 dose of sample, being all the doses applied in a unique plate, aggregating characteristics of the 2 x 2 and 5 x 1 assays. The method adopted for erythromycin microbiological assay through agar diffusion was validated, what reveals its adequacy to linearity, precision and accuracy standards. Likewise, the statistic methods employed demonstrated their accordance with the method concerning the parameters evaluated. The 3 x 1 design proved to be adequate for the dosage of erythromycin, thus being a good alternative.

QP-P-004

THE ANNUAL PRODUCT REVIEW - A GOOD WAY IN IMPROVING THE QUALITY OF DRUGS.

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Aims:

Safety and efficiency are crucial to drugs. However, before taking the medicine, consumers are not able to immediately identify which one is of good quality. A pharmaceutical factory, therefore, must take actions to maintain their product's quality which can not depend on the market screening only. The annual product review, can help pharmaceutical factories monitor their products' quality before factories release them.

Methods:

Since 2005, the annual product review has been put into practice by FortDodge Animal Health (Division of Wyeth) in Taiwan. It consists of ten parts which are summary, batches reviewed, approved documents, stability data, analytical data, annual visual inspection, adverse drug reaction, recall/salvages, action and change history. The annual product reviews compare this year's data with that of last year. For each veterinary pharmaceutical product, we review all batch records and documents about their quality of former year. The reports should be kept in the factory.

Results:

We have finished six Annual Product Reviews in 2005 and are going to finish ten reports in 2006. Judging from the comparison between the reports of this year and those of last year, we not only realized whether follow-up actions were finished but also found out the discrepancy and the current trend. We terminated the repeating problems and took the right remedial steps to correct shortcomings. According to a statistics of the customer complaints in these three year, we found that the number of the customer complaints have reduced 10% after we started performing the annual product reviews.

Conclusions:

The annual product review in a pharmaceutical factory can be a reference when setting up formulas, specifications, SOPs and SOIs. When executed and aimed at products in the market properly, it can help factories prevent customer complaints and reduce the loss in recalling products. The annual product review is really good at improving the products' quality and customer satisfaction.

QP-P-005

ORIENTATION OF MEMBRANE-BOUND MELITTIN STUDIED BY A COMBINATION OF HPLC AND LSIMS

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Melittin is a hemolytic toxin peptide of the European bee *Apis mellifera*. It is demonstrated that the membrane bound melittin molecules present a certain structure of amphipathic helix (1-22 residues) but the orientation of the helical structure of melittin on phospholipid membranes is still controversial.

Combining high performance liquid chromatography with mass spectrometry, the membrane bound melittin is analyzed through the trypsin-digested products to obtain the orientation information of melittin. As melittin bound to the LUVs without transmembrane potentials, there exists the peaks of A8-21, A8-22 in the HPLC spectrum of tryptic digestion products of melittin. It indicates that Lys7 is exposed in the solution and can be attacked by proteases. This result provides a strong proof for the assumption that the α -helix structure of melittin lies flat on the membrane surface. As melittin bound to the LUVs with a negative transmembrane potential, there is no obvious A8-21 or A8-22 peaks in the HPLC spectrum of tryptic digestion products of melittin, but there existed relatively strong A1-23 peak group. The results indicate that Lys7 must be buried in the membrane and can not be attacked by proteases, while it is relatively easy for trypsin to access the proteolytic site at the C-terminal of membrane bound melittin. So it can be supposed that the α -helix structure of melittin does not lie flat on the membrane surface under the influence of the negative transmembrane potential, and the Lys7 is no longer exposed in the solution but inserted into the membrane. It can be supposed that (i) the α -helix structure of membrane bound melittin mainly adopts the orientation of lying flat on the membrane as melittin binds to LUVs without transmembrane potential; (ii) but as melittin binds to LUVs with negative transmembrane potential, the N-terminal of melittin inserted into the membrane and the α -helix structure of membrane bound melittin probably adopts the perpendicular orientation.

QP-P-007

PREPARATION AND EVALUATION ON THE SAFETY OF INTRAVENOUS EMULSION FOR GARLIC OIL

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OBJECTIVE To prepare intravenous emulsion for garlic oil and evaluate its safety.
METHODS The intravenous emulsion for garlic oil was obtained by a high pressure homogenizer. According to the principle of SFDA and the Pharmacopoeia of the People's Republic of China (Edition 2005), the experiments of acute toxicity, hemolysis, vascular irritation, allergy and pyrogen were made. **RESULTS** The preparation was stable in quality. The particle size was 150.4 ± 14.6 nm. The LD₅₀ of intravenous injection in mice was $184.1 \text{ mg} \cdot \text{kg}^{-1}$. The preparation in different concentrations had no effects on hemolysis within 3 hours. There was no vascular irritation observed after 3 days of continuous intravenous injection of the emulsion. And the drug was free allergy and pyrogen. **CONCLUSION** The preparative technique is simple and reliable. The preparation is safe for injection.

QP-P-006

SIMULTANEOUS LC DETERMINATION OF ATORVASTATIN AND FENOFIBRATE IN TABLETS

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A simple, precise and reproducible reverse phase high performance liquid chromatographic method has been developed for the simultaneous analysis of Atorvastatin and Fenofibrate in tablets. Separation was carried out in Phenomenex, Gemini C18 column (150x 4.6 mm, 5 μ m), with the mobile phase consisted of 0.4% v/v triethyl amine (pH adjusted to 4 using dilute ortho phosphoric acid) : acetonitrile in the ratio 10: 90 % v/v. Detection of drugs were done at 245 nm and a flow rate of 1 ml/ min was used in the study. Mefenamic acid served as the internal standard. Calibration curves were linear in the range of 0.2 to 1 mg/ml and 4 to 20 mg/ml for Atorvastatin and Fenofibrate respectively. Correlation coefficient values were close to 1 proves good linear correlation between response factor and concentration. The elution order was atorvastatin (2.14 min), Mefenamic acid (2.87 min) and Fenofibrate (3.69 min). The Limit of Detection for Atorvastatin and Fenofibrate were found to be 5 and 6 ng respectively. Limit of Quantification were found to be 20 and 22 ng for Atorvastatin and Fenofibrate respectively. The precision of method was studied under intra day, inter day and repeatability studies. A low relative standard deviation value indicates that developed method has good precision. Recoveries of Atorvastatin and Fenofibrate were in the range of 98- 101 %, which shows that method is accurate and free from interferences and excipients present in formulation. The LC method was successfully applied to analysis of drugs in tablets and the estimated amount was found to be close to the labeled claim. System suitability studies and peak purity tests (Peak purity index values close to one) were performed. A complete statistical validation was also carried out proves the suitability of the method to analyze Atorvastatin and Fenofibrate simultaneously in tablets .

QP-P-008

DETERMINATION OF CARBOCYSTEINE SYRUP SHELF LIFE BY ARRHENIUS METHOD .

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Carbocysteine has been currently used as a mucolytic agent in adjunctive therapy of respiratory tract infections. The pharmaceutical industry is responsible for quality, safety and efficiency of the product during its shelf life. Shelf life can be determined through an accelerated stability study where the degradation of the drug is managed with the extrinsic factors.

According to Arrhenius, there is a relationship between temperature and chemical kinetic. The shelf life of carbocysteine syrup was determined with the Arrhenius method. The syrup assay method has been validated. The linearity, precision, accuracy, detection limit, quantitation limit, selectivity and robustness were evaluated. The samples were exposed to drastic conditions at 40 °C, 50 °C, 60 °C and 70 °C just to accelerate the degradation. The results were analyzed with the Arrhenius equation and through the graphical method. The proposed shelf life of carbocysteine syrup was 240.9 days when the dosage form is stored in appropriated conditions, 25 °C. However difference was found between the proposed shelf life and the usual shelf life of this drug, this study has showed the presence of endogenous peaks that must be more evaluated to confirm or not the presence of degradation products. On the other hand, the assay for the measurement of carbocysteine may be applied to analysis of carbocysteine syrup in routine quality control and stability studies.

QP-P-009

TRANSFER OF ANALYTICAL METHODS FOR DETERMINATION OF ASSAY AND IMPURITIES IN PARENTERAL DOSAGE FORM

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The trend in pharmaceutical industry is globalization of pharmaceutical companies. To protect quality of the product, transfer of analytical methods is necessary. Method transfer is the process that qualifies Receiving laboratory to use an analytical test procedure. It has to ensure that the staff of the Receiving laboratory is well trained and qualified to run the method and obtain comparable results.

First of all methods should be validated. Validation experiments must be done according to appropriate regulatory guidelines for method validation and described in method validation report. Validation should be done on qualified equipment.

Once when method is validated, method transfer can begin. During pre-transfer stage, receiving laboratory has to review relevant documentation. After that, method transfer protocol can be written. It is the document that is agreed upon the Transferring and Receiving laboratories which outlines the requirements of the method transfer. It is consisted of purpose, scope, responsibilities, materials and methods references, experimental design, acceptance criteria and approval page.

When method transfer protocol is signed, analyses can be done.

Next step is writing of method transfer report that contains results obtained by both parties participating in the transfer, a discussion of the results, conclusion of the transfer testing and also approval page.

In this paper will be presented transfer of analytical methods for determination of assay and impurities in parenteral dosage form of Ondansetron Injections, 2mg/mL. After all analyses were done and results were compared, it was concluded that all results meet acceptance criteria and that Receiving laboratory is qualified to use this test procedure.

QP-P-011

COMPARISON OF CAPILLARY ZONE ELECTROPHORESIS (CZE) AND HIGH PERFORMANCE LIQUID CHROMATOGRAPHY METHODS (HPLC) FOR QUANTITATIVE DETERMINATION OF FEXOFENADINE IN DRUG FORMULATIONS

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The aim of our study was to develop a rapid, simple and robust quantitative procedure, validate, and compare CZE and HPLC assays with UV detection for the determination of fexofenadine in pharmaceutical formulation. Separations HPLC system were made on a Phenomenex C18 column (150 x 4.6 mm i.d., particle size 4 µm), using isocratic elution with triethylamine 1%:ACN:methanol (50:30:20 v/v/v) pH 3.2 as the mobile phase. The detector wavelength was 210 nm. The elution was performed at a flow rate of 1.0 ml/min and experiment conducted at 40° C. Capillary zone electrophoresis separations were performed in a fused-silica uncoated capillary (48.5 cm x 50 µm i.d., Agilent) thermostated at 25°C. A voltage of 20kV was applied during analysis. The electrophoresis medium was 10 mM sodium tetraborate decahydrate 20 mM adjusted with sodium hydroxide to pH 9.3. Internal standard was nimesulide. The two methods allow direct and sensitive quantification of fexofenadine and have been shown to have good sensitivity, linearity ($r > 0.999$). The limits of detection and quantification were 0.002 and 0.05 µg.mL⁻¹ for RP-HPLC and 0.3 and 1.0 µg.mL⁻¹ for CZE, relative standard deviations (RSD) were 1.62 and 0.98% for CZE and RP-HPLC, respectively. The percentage recovery determined with CZE was 99.87% and with RP-HPLC was 99.8%. The two methods (CZE and RP-HPLC) have been successfully validated and may be considered for routine analysis of fexofenadine pharmaceutical formulation. Both methods exhibited satisfying validation results concerning sensitivity, linear range, detection limit, reproducibility, accuracy and precision (RSD < 2%).

QP-P-010

HIGH-PERFORMANCE LIQUID CHROMATOGRAPHIC ASSAY OF BENZYL ALCOHOL AS A PRESERVATIVE IN TOPICAL FORMULATION

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Stability indicated HPLC method for determination of benzyl alcohol as a preservative in terbinafine HCl topical (cream) formulation is developed and validated. The method is based on the method for determination of terbinafine impurities in terbinafine hydrochloride substance published in *Pharmaceutica* Vol.16, No.1, January 2004.

Benzyl alcohol is an antimicrobial preservative used in cosmetics, foods, and a wide range of pharmaceutical formulations, including oral and parenteral preparations, at concentration up to 2.0% v/v. In cosmetics, concentrations up to 3.0% v/v may be used as a preservative. Concentrations of 5% v/v or more are employed as a solubizer, while a 10% v/v solution is used as a disinfectant.

Terbinafine HCl is a synthetic antifungal agent.

Chromatographic conditions: cream was dissolved in a mixture of acetonitrile, methanol and water in the ratio 50 : 25 : 25 with final concentration 0.5 mg/ml of benzyl alcohol and analysed on Agilent 1100 instrument with DAD detector (260 nm) on column RP-18, 250*4.6 mm. Mobile phase was mixture of 0.01M K₂HPO₄ and organic phase (acetonitrile/methanol 67/33 v/v).

Method was validated in terms of selectivity, linearity, accuracy, precision (measurement repeatability and intermediate precision), stability of standard and sample solutions and robustness. In conclusion, the method is suitable for tracking the content of benzyl alcohol in Terbinafine cream 1% during stability testing.

QP-P-012

SIMPLE AND RELIABLE HPLC METHOD OF ATENOLOL DETERMINATION IN PHARMACEUTICAL DOSAGE FORMS

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This work describes a new, fully validated, simple, rapid, selective, and sensitive HPLC method with diode array detection for the direct determination of Atenolol in pharmaceutical dosage forms without any ion-pairing agent on the mobile phase. A survey of literature has revealed several analytical methods for the determination of atenolol in dosage forms including high-performance liquid chromatography (HPLC) utilizing heptansulphonic acid, HPLC adopted by the United States Pharmacopoeia was based on the mobile phase containing heptanosulfonate as ion-pairing agent, which is very expensive.

The mobile phase employed was 10 mM ammonium acetate buffer (pH 7,0) and acetonitrile (80:20 v/v). The samples of 20 µl were injected onto Purospher Star® RP-18 (250 mm x 4.6 mm, 5 µm particle size) column, Shimadzu LC-20AT HPLC system, equipped with a model LC-20AT pump, oven for column model CTO-10AS. The flow rate was 0.8 ml.min⁻¹. The retention time was 2.5 min for atenolol. The samples were detected at 275 nm. The assay was linear in the concentration range 125 – 375 µg.mL⁻¹

The representative linear equation was $y = 2E-07x - 0,0091$, with a correlation coefficient ($r = 0,9989$) highly significant for the method. The precision of the method was determined by repeatability (CV 0.88%) and intermediate precision (CV 0.96%). The accuracy of the method was determined and the mean recovery was found to be 99.80% indicating an agreement between the true value and the value found. The HPLC method for the determination of atenolol in tablets was found to be simple, rapid, precise, accurate and sensitive. It was successfully applied to the analysis of atenolol pharmaceutical preparation in routine quality control.

QP-P-013

VALIDATION OF HPLC AND UV SPECTROPHOTOMETRY DETERMINATIONS OF CEFIXIME IN CAPSULES

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In this study two different methods, HPLC and UV spectrophotometry, are presented and validated for the determination of cefixime in capsules, a known antibiotic, with excellent efficacy in the treatment of urinary and respiratory infections. Cefixime was determined by HPLC method using a LiChrospher 100 RP-18 (5mm) column with mobile phase consisting of pH 7.0 potassium phosphate buffer - acetonitrile (90:10 v/v) at a flow rate of 0.4 ml.min⁻¹. The concentration range was 5.0-35.0 mg.ml⁻¹. The spectrophotometric UV method was performed in pH 6.0 potassium phosphate buffer in concentration range 2.0-10.0 mg ml⁻¹. Both validated methods are linear, precise, accurate, sensitive and can be directly and easily applied to determination of bulk drugs and the pharmaceutical preparations of cefixime.

QP-P-014

IMPORTANCE OF THE EVALUATION OF THE FLOUR LIFE-OF-SHELF STRENGTHENED WITH FOLIC ACID IN THE PREVENTION OF DEFECTS OF THE NEURAL PIPE IN PELOTAS-RS

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Many scientific works point on the importance of the folic acid in the prevention of defects of the neural pipe. In the attempt of that the population improves the ingest of this vitamin has been praised the enrichment of flours so that if it obtains to prevent between 50 and 70% of the malformations of the neural pipe. Exactly thus, the rigorous control of these flours becomes necessary therefore, can occur losses during the manufacture processes and stockage. Factors as temperature, light, pH, oxidantes presence of catalysers and agents are responsible for the degradation of the folic acid being of this form, sufficiently useful the studies on the stability of the folic acid in flours, in the direction to guarantee the quality until the end of the validity stated period, to guide the producer in the necessary super dosage, for the production, and from the best conditions of packing, it has carried and storage. This study it has as objective to quantify the folic acid in existing flours of wheat in the market of Pellets, verifying if the levels of folic acid in wheat flours are in accordance with the levels praised in the legislation of the National Sanitary Monitoring Agency (ANVISA) and to evaluate the stability of the folic acid to the long one of the period of 4 months of validity of flours.

QP-P-015

QUALITATIVE AND QUANTITATIVE ANALYSIS OF THE FOLIC ACID COMMERCIALIZED IN PHARMACIES GALENICAS IN THE BAGE CITY

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In the present time Quality it is the word of order and it must be inherent to any product or rendering of services. For the skillful pharmacy it is not different, being the basic quality for its survival, the professional respect and the guarantee of a pharmacological therapy effective for the patient. The skillful sector grew very and currently already it exists all about 5 a thousand pharmacies in the Brazil. However, which had not the conformity of some of the pharmaceutical establishments with demanded minimum standards of quality, the sector that in such a way suffers much preconception on the part from the population as on the part of the excessively professional ones of the health and, in many cases the industrialized medicine is considered of better quality. One becomes, therefore primordial the establishment of the conditions of the products gifts in the market is on the part of governmental institutions of fiscalization, particular universities or institutions that have capacity technique and physics for accomplishment of analytical techniques that guarantee the degree of quality of such products. This work carries through the study of the quality of the capsules of folic acid commercialized in pharmacies of manipulation of the city of Bage, tracing itself thus a parameter of quality between the same ones, having as reference the medicine industrialized commercialized with name of Folin, acquired in one would drug in the city of Bage. The necessity of external controls of quality of medicines was verified to prevent errors with medications and, to assist the population in the medication use with quality guaranteed

QP-P-016

EVALUATION OF THE QUALITY OF MALEATO OF ENALAPRIL IN INDUSTRIALIZED AND MANIPULATED PHARMACEUTICAL FORMS

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The medicine preparation compels to a rigorous verification how much it is possible, given to the moral and legal aspects related they, where any error can express risk for patient. Thus the pharmaceutical control of quality must guarantee the conformity of the medicine with the specifications that say respect to it, as well as its harmless and effectiveness. The guarantee of the service and product quality of health is evidenced mainly in chronic pathology where it has the necessity of the use of these products and services for long periods of time. The high blood pressure is one of the pathology of bigger prevalence in the world. In Brazil, high blood pressure, also, possesses high prevalence, for the control is used, in the treatment with preventives drugs. The useful medicines in the treatment of this pathology include chemical structures widely varied, being able to be classified in function of its mechanism of action. The enalapril is an example, therefore, it acts for diverse mechanisms. In this work they had been analyzed and evaluated the possible variations in the product quality that they possess as active principle the maleato of enalapril, as much in the industrialized pharmaceutical forms how much manipulated in the intention of assisting in the guarantee of the quality of available medicines the population, verifying itself it necessity of external controls of quality for attainment of minimum levels of quality of available medicines in the market.

QP-P-017

THE PRESERVATION OF THE FOLIC ACID IN THE PARBOLIZATION OF THE RICE

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The parbolization is an improvement method that increased more than 4 for 20% of the total of rice consumed in Brazil in last the two decades. In this process it has increase of the nutritional value and the grains more present accented flavor and odor of the one than the polishing white rice. Recent studies disclose that the folic acid, essential vitamin of the Complex B, have important metabolic functions for maintenance of the health human being, mainly as cofactor of enzymes that synthesize the DNA and the RNA. Its scarce ingest of vitamins causes serious fetais illnesses, as defects in the closing of the neural pipe, and the best form to get this nutrient is through the ingest of foods the base of grains. In this work the texts of folic acid in grains of parboilizado rice are investigated and the effect of the operations of industrial improvement on the preservation of the folic acid in the attempt to trace a parallel enter the legal regulation proposal for the ANVISA of Brazilian flour blockhouse with folic acid x industrial improvement and guarantee of the product quality offered to the consumer acting together to the producers local of rice in the maintenance of title of greater center of rice producers of granted America Latin the city of Pellets. Importance of metodological alternatives in the evaluation of products for the guarantee of the final quality of these products is verified it and, of the legal adequacy of existing products in the market

IM-P-001

INCREASED PHOTODYNAMIC AND ANTIMICROBIAL ACTION OF METHYLENE BLUE INDUCED BY RED LED LAMPS EXPOSURE.

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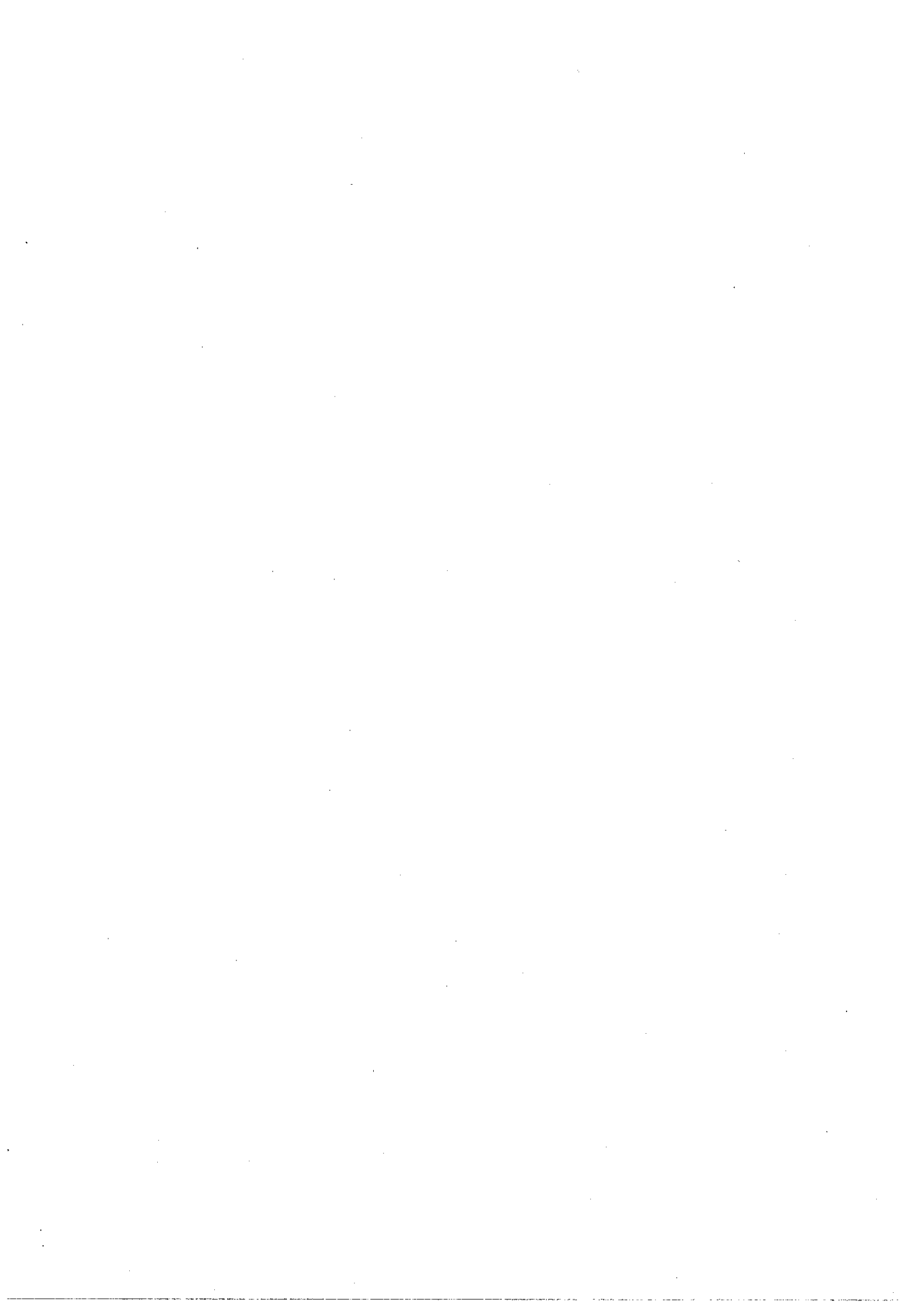
Photodynamic therapy (PDT) is a technique that uses a photosensitizing compound, activated at a specific wavelength of visible light, to destroy a targeted cell via strong oxidizers that cause cellular damage, membrane lysis, and protein inactivation. One of the most well known photosensitizers is methylene blue (MB), which has photooxidation properties against microorganisms. Considering that the most disadvantageous aspect of PDT is the high cost of treatment that uses laser as light device, the objective of this paper is to propose the use of red LED lamps as an alternative to PDT, and to check their effectiveness against microorganisms using MB as photosensitizer. Assays with and without LED lamp exposure for 10, 20 and 30 minutes were carried out in plates containing *Staphylococcus aureus* (ATCC 26923), *Escherichia coli* (ATCC 26922) or *Candida albicans* (ATCC 90028) in Mullen Hinton Broth, with MB at concentrations of 10 to 200 mg/ml. The power of the LED lamps was 5mW, with maximum absorption at 660 nm (the same absorption region as MB). In the control groups (cultures without MB), no effect was observed with LED lamp exposure. MB without light induced a progressive inhibition of cell growth from 10 to 200 mg/ml, while with LED light exposure all cells were inhibited. In ten minutes of light exposure and 50 or 60 mg/ml of MB, the % of inhibition was 92.96% for *S.aureus*, 96.9% for *E.coli* and 93.33 % for *C.albicans*. The red LED lamp is a promising light device for PDT that can effectively inhibit bacteria and yeast growth.

IM-P-002

FREQUENCIES OF CYP2D6 *10 AND *14 ALLELES AND THE INFLUENCE ON THE METABOLIC ACTIVITY IN A HEALTHY HEALTHY CHINESE POPULATION

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AIM: To study the gene frequencies of CYP2D6 *10 and *14 alleles in a healthy Chinese population, and the influence of the two alleles on the metabolic activity of CYP2D6. METHODS: The CYP2D6*10 and *14 genotypes of 295 healthy Chinese subjects were determined by allele specific amplification established in our lab. The phenotypes of 131 subjects were determined. RESULTS: There are 10 subjects with *14 allele, including a homozygous for *14 allele. The gene frequency of *10 and *14 alleles were 55.8% and 1.8%, respectively. The metabolic ratio (MR) of dextromethorphan (DM) in 131 subjects was 0.032 ± 0.106 . The MR of *1/*1, *1/*10, *10/*10, *1/*14, *10/*14 and *14/*14 group were 0.007 ± 0.012 , 0.009 ± 0.010 , 0.042 ± 0.029 , 0.065, 0.14 and 1.186, respectively. The MR of homozygous for *14 group, which is found in a poor metabolizer (PM), was higher than those of *1/*1, *1/*10 or *10/*10 groups ($P < 0.001$). CONCLUSION: The CYP2D6*10 and *14 allele have great impact on the metabolic activity of CYP2D6, and CYP2D6*14 allele may be the cause of the PM in Chinese subjects.



Author Index

Author	Code	page	Author	Code	page
Abdel Hameed, R	IPS-P-005	161	Amaro, L	CPS-P-017	104
Abduvasitova, NP	LMCS-P-003	176	Amaro, L	CPS-P-020	104
Abduvasitova, NP	LMCS-P-010	178	Amorim, MV	IPS-P-040	169
Åberg, M	CPS-P-079	119	Anand Babu, D	IPS-P-020	164
Abriata, JP	CPS-P-035	108	Anderson, C	CPS-P-008	101
Abriata, JP	CPS-P-070	117	Anderson, C	CPS-P-009	102
Abriata, JP	CPS-P-071	117	Anderson, CW	ABS G13-2	67
Accioly de Lima e Moura, TF	PI-P-027	186	Anderson, CW	BIO G01-0	43
Addo-Atuah, J	PI-O-005	189	Anderson, CW	BIO G13	66
Addo-Atuah, J	PI-O-005	189	Anderson, CW	BIO P4-0	13
Adenot, I	CPS-P-001	100	Anderson, L	BIO G18-0	75
Adenot, I	CPS-P-002	100	Andersson, Å	HPS-P-033	142
Adenot, I	CPS-P-037	109	Andersson, Å	PI-P-017	184
Adriano, M	HPS-P-054	147	Andersson, A-M	CPS-P-032	107
Afonso, R, da S.	CPS-P-123	130	Andersson, I-L	CPS-P-022	105
Agerholm, H	CPS-P-095	123	Andreev, G	HPS-P-025	140
Agnes LF, C	CPS-P-073	118	Anil, A	HPS-P-012	136
Agnez, L	IPS-P-040	169	Ansari-Jaberi, Z	IPS-O-009	175
Ahel, VA	HPS-P-051	146	Antic, AM	NS-P-008	197
Ahsan, M	PI-P-001	180	Antunovic, M	HPS-P-031	141
Airaksinen, M	ABS G13-3	67	Antunovic, M	HPS-P-032	141
Airaksinen, M	ABS G15-4	70	Antunovic, M	LMCS-P-005	177
Airaksinen, M	BIO G13	66	Arai, K	CPS-P-119	129
Airaksinen, M	BIO G15-4	69	Arancibia, O	ABS G02-1	48
Åkerlund, E	CPS-P-065	116	Arancibia, O	ABS S2-1	25
Akunyili, N	ABS PS1-3	17	Arancibia, O	BIO G02-1	46
Akunyili, N	BIO PS1-3	16	Arancibia, O	BIO S2-1	23
Alan Batista Cavalcante, E	CPS-P-004	100	Aranda da Silva, JA	AS-O-008	95
Albuquerque, MM	IPS-P-038	169	Aranda da Silva, JA	CPS-P-109	127
Alcântara de Sousa, MC	NS-P-011	198	Arandjelovic, A	LMCS-P-004	176
Alcantara, M	HPS-P-030	141	Arandjelovic, A	LMCS-P-005	177
Aleksic, AD	HPS-P-031	141	Araújo Góis, RAG	PI-P-018	184
Aleksic, AD	HPS-P-032	141	Araújo, BM	CPS-P-003	100
Aleksic, K	IPS-P-035	168	Araújo, D	PI-P-030	187
Alencar, JRB	IPS-P-036	168	Araujo, I	IPS-P-043	170
Alencar, JRB	IPS-P-037	169	Araujo, I	IPS-P-044	170
Aliaga, A	CPS-P-019	104	Araujo, I	IPS-P-049	172
Alibajraktarevic, A	HPS-P-010	136	Araujo, I	IPS-P-050	172
Alibajraktarevic, AA	PP-P-006	206	Araújo, I	IPS-P-041	170
Aljamal, M	AS-O-004	94	Araújo, I	IPS-P-042	170
Aljamal, M	PP-P-005	206	Araújo, I	IPS-P-047	171
Almeida, AM	HPS-P-065	150	Araújo, I	IPS-P-048	171
Almeida, D	IPS-P-042	170	Araújo, JH	IPS-P-050	172
Almeida, D	IPS-P-046	171	Araújo, PS	CPS-P-072	117
Almeida, RS	NR-P-004	201	Araújo, PS	CPS-P-089	122
Almeida, S	PI-P-015	183	Araújo, PS	HPS-P-053	147
Almitwazi, A	AS-O-004	94	Araújo, PS	HPS-P-054	147
Alrashed, S	ABS G24	89	Araújo, PS	HPS-P-055	147
Alrashed, S	AS-O-004	94	Araújo, PS	HPS-P-072	151
Altagracia, M	APS-P-007	97	Araújo, PS	HPS-P-091	156
Altagracia-Martinez, M	APS-P-002	96	Araújo, PS	HPS-P-092	156
Altagracia-Martinez, M	APS-P-002	96	Araújo, PS	HPS-P-093	157
Alves, GL	BB-P-017	195	Araújo, PS	HPS-P-094	157
Alves, GL	CPS-P-092	122	Araújo, PS	PI-P-019	184
Alves, J	HPS-P-072	151	Armando, PD	CPS-P-016	103
Alves, VC	HPS-P-091	156	Armando, PD	HPS-P-095	157
Amaral, LC, do	CPS-P-003	100	Ashokraj, Y	IPS-P-017	164
Amariz, AA	PI-P-029	187	Ashokraj, Y	IPS-P-019	164

Author Index

Author	Code	page	Author	Code	page
Ashokraj, Y	IPS-P-021	165	Bertoldi, A	PP-P-017	209
Augustsson, J	HPS-P-023	139	Betancourt Bravo, A	QP-P-001	210
Augustsson, J	PI-P-016	183	Betancourt Bravo, A	QP-P-002	210
Ax, F	CPS-P-032	107	Bezerra de Meneses, D	HPS-P-089	156
Azizov, UM	LMCS-P-003	176	Bhalla, N	HPS-P-090	156
Baby, AR	BB-P-004	191	Bhandari, KH	IPS-O-007	174
Bacic, IB	HPS-P-049	146	Bhandari, KH	IPS-P-010	162
Bacic, IB	HPS-P-050	146	Bhandari, KH	IPS-P-024	165
Baisch, AL	PP-P-017	209	Bhandari, KH	IPS-P-026	166
Balakrishnan, P	IPS-O-007	174	Bhandari, KH	IPS-P-028	166
Balakrishnan, P	IPS-P-010	162	Bharadwaj, V	IPS-P-018	164
Balakrishnan, P	IPS-P-027	166	Bharatam, P	IPS-P-023	165
Balakrishnan, P	IPS-P-028	166	Bhaskar, K	IPS-P-011	162
Ball, P	HPS-P-063	149	Bhattacharya, S	NS-P-009	198
Balter, H	NR-P-003	201	Bhojraj, S	ABS S4-1	29
Balter, HS	ABS S6-10	37	Bhojraj, S	BIO S4-1	28
Balter, HS	BIO S6-7	33	Binakaj, BZ	PP-P-006	206
Bandal, RS	CBS-P-001	98	Binakaj, BZ	PP-P-006	206
Bandal, RS	HPS-P-003	134	Binakaj, Z	HPS-P-010	136
Bangert, C	CPS-P-085	121	Biondo, CEG	IM-P-001	215
Bapurao, T	IPS-P-019	164	Bittencourt, M	CPS-P-121	130
Barbosa, L	IPS-P-045	171	Bittencourt, M	CPS-P-122	130
Barbosa, M	HPS-P-054	147	Bittencourt, M	CPS-P-123	130
Bardot, S	MEPS-P-001	179	Bittencourt, M	HPS-P-102	159
Barends, DM	BIO S2-0	23	Bittencourt, M	PI-P-030	187
Barker, RW	ABS G11-3	65	Bittencourt, M	PP-P-019	209
Barker, RW	BIO G11-3	64	Bittencourt, M	PP-P-020	209
Baron, I	CPS-P-087	121	Bittencourt, M	QP-P-013	213
Barr, J	AS-P-004	91	Bittencourt, M	QP-P-014	213
Barreto, NV	HPS-P-093	157	Bittencourt, M	QP-P-015	213
Barros Vasconcellos, PBV	BB-P-019	195	Bittencourt, M	QP-P-016	213
Barsun, M	QP-P-010	212	Bittencourt, M	QP-P-017	214
Barth, T	QP-P-011	212	Björk, H	ABS G11-1	65
Basaric, D	CPS-P-048	111	Björk, H	BIO G11-1	63
Basic, I	HP-P-001	130	Björnsdóttir, I	PI-O-006	189
Basic, Z	LMCS-P-004	176	Blanc, A	CPS-P-061	115
Bavcar, V	CPS-P-010	102	Blanchet, F	CPS-P-001	100
Bazotte, RB	ABS P2-5	10	Blanchet, F	CPS-P-002	100
Bazotte, RB	BIO P2-4	8	Blanchet, F	CPS-P-061	115
Becic, BF	PP-P-006	206	Blekic, J	CPS-P-060	114
Beck, RCR	IPS-P-034	168	Boardman, H	CPS-P-008	101
Beckman, A	CPS-P-098	124	Boardman, H	CPS-P-009	102
Beckman, A	CPS-P-098	124	Bolard, J	IPS-P-049	172
Behzadi, M	HPS-P-088	155	Bond, C	ABS G18-1	77
Bell, JS	ABS G01-4	45	Bond, C	BIO G18-1	75
Bell, JS	ABS G15-5	71	Bootman, J	ABS P4-3	15
Bell, JS	BIO G01-4	44	Bootman, J	BIO P4-3	13
Bell, JS	BIO G15-5	69	Boraei, NA	IPS-O-001	173
Bellozi, MS	CPS-P-003	100	Borges, F	NS-P-010	198
Bembrilla, L	CPS-P-110	127	Borges, W	PI-P-015	183
Bengtsson, U	PI-P-017	184	Bortoletto, TC	HPS-P-030	141
Benincá, JP	NS-P-017	200	Boscariol, MR	IPS-P-002	160
Benrimoj, SI	ABS G05-5	56	Bousova, I	NS-P-001	196
Benrimoj, SI	BIO G05-5	54	Braga Pires, G	CPS-P-005	101
Benrimoj, SI	HPS-P-008	135	Brasil, A	CPS-P-107	126
Berbare, M	PI-P-015	183	Brasil, ASC	CPS-P-089	122
Berbare, MHA	HPS-P-030	141	Brasil, ASC	HPS-P-094	157
Bernsten, C	CPS-P-098	124	Brassica, SC	HPS-P-027	140

Author Index

Author	Code	page	Author	Code	page
Bravo, MN	IPS-O-004	173	Carvalho Queiroz Melo, CQM	BB-P-008	192
Bricola, AAO	CPS-P-099	124	Carvalho, J	IPS-P-049	172
Bricola, AAO	PI-P-023	185	Carvalho, J	IPS-P-050	172
Bricola, AAO	PP-P-013	208	Casper, A	CPS-P-059	114
Bridell, GB	ABS G20-3	81	Cassiani, SHB	HPS-P-098	158
Bridell, GB	BIO G20-3	80	Cassiani, SHB	HPS-P-099	158
Brien, J	HPS-P-008	135	Cassiani, SHB	HPS-P-101	159
Brito, CCU	HPS-P-072	151	Castel-Branco, MM	BB-P-017	195
Bronze, MR	IPS-O-004	173	Castro, L	PP-P-018	209
Brown, LB	CPS-P-012	102	Castro, LLC	PP-P-011	207
Bryant, L	CPS-P-025	106	Cater, N	CPS-P-086	121
Bryant, L	CPS-P-026	106	Catizone, CA	ABS P3-3	12
Bryant, L	CPS-P-055	113	Catizone, CA	BIO P3-3	11
Btaiche, F	HPS-P-024	139	Cavanaugh, TMC	IPS-O-012	175
Bucalic, M	PP-P-007	206	Cebotarenco, N	PI-O-003	188
Bucalic, M	PP-P-009	207	Cecillon, D	MEPS-P-002	179
Buchmann, M	CPS-P-054	113	Cedillo-Ramírez, R	IPS-P-001	160
Buckle Nordor, RA	ABS G17-3	74	Cesar Galindo Bedor, DCGB	BB-P-018	195
Buckle Nordor, RA	BIO G17-4	73	Cesar Galindo Bedor, DCGB	BB-P-019	195
BUGNON, O	CPS-P-054	113	Cesar Galindo Bedor, DCGB	BB-P-020	195
Bugnon, O	CPS-P-083	120	Cetulean, M	PI-O-003	188
Bugnon, O	CPS-P-084	120	Chan, TS	HPS-P-062	149
Bugnon, O	CPS-P-091	122	Chan, XH	GPP	90
Bušelic, R	CPS-P-102	125	Chan, YY	HPS-P-073	152
Bush, PJ	PI-O-003	188	Chan, Y-Y	APS-P-005	97
Buys, GM	IPS-P-012	162	Chan, Y-Y	APS-P-006	97
Cabral Pereira Pinto, DCPD	PI-P-018	184	Chang, CJ	HPS-P-081	154
Cabral, LM	IPS-P-031	167	Chang, CJ	PI-P-026	186
Cabral, P	NR-P-003	201	Chang, CW	HPS-P-035	142
Cai, W	IM-P-002	215	Chang, FC	HPS-P-084	154
Caillier, S	CPS-P-087	121	Chang, HJ	HPS-P-021	139
Calvo, MV	HPS-P-074	152	Chang, HL	HPS-P-043	144
Caminha, C	BB-P-009	193	Chang, JC	HPS-P-079	153
Campos, MMC	PP-P-002	205	Chang, MH	HPS-P-071	151
Capilla, P	CPS-P-017	104	Chang, SC	IPS-P-030	167
Capilla, P	CPS-P-019	104	Chao, C	HPS-P-047	145
Capilla, P	CPS-P-020	104	Chastinet, H	CPS-P-089	122
Capilla, P	CPS-P-042	110	Chauve, M	CPS-P-087	121
Capilla, P	CPS-P-043	110	Chen, B	IM-P-002	215
Caramona, M	CPS-P-051	112	Chen, BY	HPS-P-078	153
Caramona, MM	BB-P-017	195	Chen, C	QP-P-004	210
Caramona, MM	CPS-P-088	121	Chen, CH	APS-P-004	96
Caramona, MM	CPS-P-092	122	Chen, CY	LMCS-P-006	177
Caramona, MM	HPS-P-065	150	Chen, F	ABS G01-2	45
Caramona, MM	LMCS-P-008	177	Chen, F	ABS G18-2	77
Caramona, MM	NR-P-004	201	Chen, F	ABS P2-1	9
Caramona, MM	NR-P-005	202	Chen, F	BIO G01-2	43
Carapinha, JL	BIO G21-4	83	Chen, F	BIO G18-2	75
Carbonell, J	CPS-P-017	104	Chen, F	BIO P2-1	8
Carbonell, J	CPS-P-020	104	Chen, HL	HPS-P-066	150
Cardão, M	PI-P-021	185	Chen, HM	HPS-P-079	153
Cardenas, E	APS-P-007	97	Chen, HY	HPS-P-059	148
Carl, S	HPS-P-011	136	Chen, HY	HPS-P-062	149
Carl, S	HPS-P-013	137	Chen, HY	HPS-P-079	153
Carlsen, BEC	CPS-P-036	108	Chen, H-Y	APS-P-005	97
Carriço, A	IPS-P-049	172	Chen, H-Y	HPS-P-058	148
Carriço, A	IPS-P-050	172	Chen, H-Y	HPS-P-067	150
Carvalhas, P	PI-P-021	185	Chen, H-Y	HPS-P-073	152

Author Index

Author	Code	page	Author	Code	page
Chen, I	HPS-P-040	143	Chu, YL	HPS-P-084	154
Chen, J	HPS-P-026	140	Chuamanochan, P	CPS-P-112	127
Chen, JD	HPS-P-052	146	Chuang, MH	HPS-P-084	154
Chen, JD	HPS-P-081	154	Chuang, YP	PI-P-026	186
Chen, JD	PI-P-026	186	Cirne de Oliveira, TCO	PI-P-018	184
Chen, LW	HPS-P-064	149	Clair, P	MEPS-P-001	179
Chen, R	QP-P-004	210	Clemens, NT	IPS-P-013	163
Chen, W	QP-P-004	210	Cohen-Solal, F	PI-P-005	181
Chen, WJ	HPS-P-022	139	Cohen-Solal, F	PI-P-006	181
Chen, YC	CPS-P-075	118	Colas, C	PI-P-005	181
Chen, YH	HPS-P-022	139	Colas, C	PI-P-006	181
Chen, YH	HPS-P-064	149	Cole, N	ABS S6-00	35
Cheng, HC	HPS-P-078	153	Cole, N	BIO S6-0	32
Cheng, HF	HPS-P-069	151	Consiglieri, VO	BB-P-004	191
Cheng, YD	CBS-P-003	98	Consiglieri, VO	IPS-O-006	174
Cheng, YD	CBS-P-004	98	Contente, M	IPS-O-004	173
Cheng, YD	HPS-P-035	142	Cooper, J	CPS-P-066	116
Chiang, CCH	HPS-P-016	137	Cooper, J	PI-O-008	189
Chiang, CHC	HPS-P-016	137	Cordeiro, A	HPS-P-030	141
Chiang, YC	HPS-P-059	148	Correa-Salde, VA	CPS-P-103	125
Chiang, YC	IPS-P-030	167	Cortez, LER	NS-P-013	199
Chiao, YJ	HPS-P-081	154	Cosic, S	HPS-P-032	141
Chiba, T	HPS-P-056	147	Costa de Carvalho, KCC	PI-P-018	184
Chien, CS	LMCS-P-006	177	Costa, AA	PP-P-019	209
Chien, H-Y	HPS-P-057	148	Costa, AA	PP-P-020	209
Chien, H-Y	HPS-P-058	148	Costa, NE	NR-P-004	201
Chien, H-Y	HPS-P-067	150	Costa, NE	NR-P-005	202
Chien, SC	HPS-P-026	140	Costa, TCB	HPS-P-092	156
Chien, SY	APS-P-004	96	Coster, G	CPS-P-025	106
Chikayuki, O	HPS-P-029	141	Coster, G	CPS-P-026	106
Chin, FS	LMCS-P-006	177	Costi, C	CBS-P-005	99
Chinwong, D	CPS-P-111	127	Craignou, J-L	CPS-P-002	100
Chinwong, D	CPS-P-112	127	Craignou, JLC	CPS-P-001	100
Chinwong, D	CPS-P-113	128	Cristina de Souza, V	BB-P-018	195
Chinwong, S	CPS-P-111	127	Cristina de Souza, V	BB-P-019	195
Chinwong, S	CPS-P-112	127	Cristina de Souza, V	BB-P-020	195
Chinwong, S	CPS-P-113	128	Crommelin, DJA	ABS S3-2	27
Chiu, C-P	APS-P-006	97	Crommelin, DJA	ABS S5	31
Chiu, MJ	NS-P-005	197	Crommelin, DJA	BIO S3	26
Chiu, MJ	PI-P-013	183	Crosbie, D	PI-O-008	189
Cho, J	CPS-P-018	104	Cruz, R	APS-P-007	97
Choi, H-G	IPS-O-007	174	Cruz, RA	PI-P-027	186
Choi, H-G	IPS-P-007	161	Cui, L	AS-O-002	94
Choi, H-G	IPS-P-008	161	Culig, J	PP-P-007	206
Choi, H-G	IPS-P-009	162	Culig, J	PP-P-008	206
Choi, H-G	IPS-P-010	162	Culig, J	PP-P-009	207
Choi, H-G	IPS-P-024	165	Cunha, AP	PI-P-023	185
Choi, H-G	IPS-P-025	166	Cunha, AP	PP-P-013	208
Choi, H-G	IPS-P-026	166	Curtis, S	HPS-P-090	156
Choi, H-G	IPS-P-027	166	da Costa, DSM	CPS-P-123	130
Choi, H-G	IPS-P-028	166	Da Silva Gram, SG	BB-P-009	193
Choi, J-Y	IPS-P-008	161	Da Silveira Júnior, LS	PI-P-027	186
Choi, J-Y	IPS-P-024	165	Dada, O	CPS-P-117	129
Choi, J-Y	IPS-P-025	166	Dahdal, WYD	BIO G17-0	72
Choi, J-Y	IPS-P-026	166	Dai, F	LMCS-P-011	178
Christensen, BP	CPS-P-029	107	Dal' Maso, A	BB-P-015	194
Chu, K	HPS-P-104	159	Dal' Maso, A	QP-P-008	211
Chu, Y	HPS-P-104	159	Dalmora, SL	QP-P-011	212

Author Index

Author	Code	page	Author	Code	page
Damasceno, B	IPS-P-042	170	Djukic, Lj	CPS-P-044	110
Dantas de Medeiros, IDM	PI-P-018	184	Djukic, Lj	PI-P-007	181
Dartnell, J	ABS G22-3	87	Djukic, Lj	PI-P-007	181
Dartnell, J	BIO G22-2	86	Djurovic, D	CPS-P-013	103
Dartnell, J	PI-O-001	188	Djurovic, D	NS-P-008	197
Darwish, IA	IPS-O-001	173	Dodoo, NO	BIO S7	39
Dayana Nascimento, D	HPS-P-085	155	D'Oliveira, PS	NS-P-013	199
De Amorim, FER	HPS-P-100	158	Dominguez-Gil, A	HPS-P-074	152
De Aquino Fonseca, IAAF	PI-P-018	184	Dominici, V	IPS-P-042	170
De Araújo Almeida, FAAA	PI-P-018	184	Dragicevic Curic, N	CPS-P-106	126
De Araújo Ferreira, TJ	PI-P-027	186	Dreux, C	CPS-P-061	115
De Araújo Teixeira, LT	PI-P-027	186	Drsata, J	AS-P-003	91
De Boer, A	AS-O-001	94	Drsata, J	NS-P-001	196
De Gier, JJ	ABS G09-2	60	Du Pasquier, S	CPS-P-084	120
De Gier, JJ	ABS P4-4	15	Duarte, R, da S.	HPS-P-102	159
De Gier, JJ	BIO G09-3	59	Duckham, C	PB-P-006	204
De Gier, JJ	BIO P4-4	14	Duggan, C	ABS R2-1	4
De Liz, R	NS-P-016	199	Duggan, C	BIO R2-1	2
De Liz, R	NS-P-017	200	Dujic, T	CBS-P-006	99
De Oliveira, G	BIO S7	39	Duncan, GJ	ABS G13-1	67
De Paula Jr, W	PI-P-029	187	Duncan, GJ	BIO G13	66
Decollogny, A	CPS-P-054	113	Dunlop, J	CPS-P-055	113
Dekker, TG	BB-P-014	194	Dunlop, JA	ABS G18-4	77
Del Castillo, B	AS-P-001	91	Duus Nielsen, I	AS-O-005	95
Del Castillo, B	AS-P-002	91	Edler, E	CPS-P-079	119
Dela, K	CPS-P-069	117	Eduardo M. de Souza, CEMS	BB-P-018	195
Deljkic, DM	PP-P-006	206	Eduardo M. de Souza, CEMS	BB-P-019	195
Deljkic, M	HPS-P-010	136	Eduardo M. de Souza, CEMS	BB-P-020	195
Delmas, J-L	CPS-P-049	112	Egito, ES	IPS-P-040	169
D'Emanuele, A	BIO G20-0	79	Egito, ES	IPS-P-041	170
Deng, S	HPS-P-041	144	Egito, ES	IPS-P-042	170
Deng, ST	CBS-P-004	98	Egito, ES	IPS-P-043	170
Deng, ST	HPS-P-035	142	Egito, ES	IPS-P-044	170
Deng, ST	HPS-P-040	143	Egito, ES	IPS-P-045	171
Deng, ST	HPS-P-060	148	Egito, ES	IPS-P-046	171
Deng, ST	HPS-P-064	149	Egito, ES	IPS-P-047	171
Deng, ST	HPS-P-066	150	Egito, ES	IPS-P-048	171
Deng, ST	HPS-P-068	150	Egito, ES	IPS-P-049	172
Deng, ST	HPS-P-069	151	Egito, ES	IPS-P-050	172
Deng, ST	HPS-P-070	151	Eiichi Akaho,	ABS G22-5	88
Deng, ST	HPS-P-071	151	Einarson, T	AS-P-005	92
Deshpande, MM	CBS-P-001	98	Einarson, T	AS-P-006	92
Deshpande, MM	HPS-P-003	134	Eklund, LH	HP-O	133
Desjardin, O	AS-P-005	92	Eksborg, S	HPS-P-033	142
Desjardin, O	AS-P-006	92	Eksborg, SE	HPS-P-023	139
Deus, JPF	CPS-P-003	100	Eleamen, E	IPS-P-043	170
Dhillon, S	HPS-P-090	156	Eleamen, E	IPS-P-044	170
Dias da Costa Alves, N	IPS-O-008	175	Eljuga, D	HP-P-001	130
Dias, MF	PP-P-019	209	EL-Khordagui, LK	IPS-O-001	173
Dias, MF	PP-P-020	209	Enare, E	CPS-P-078	119
Diedrichsen, EKD	ABS G01-1	45	Eniojukan, J	CPS-P-118	129
Diedrichsen, EKD	BIO G01-1	43	Eriksson, LV	CPS-P-022	105
Diedrichsen, EKD	BIO G05-6	54	Ernestam, SE	HPS-P-023	139
Digné, K	CPS-P-078	119	Espelho, SC	NS-P-013	199
Dimovski, D	HPS-P-083	154	F. Rigod, J	PI-P-002	180
Diniz, AMD	PI-P-018	184	Fagundes, AJ	QP-P-015	213
Diniz, C	NS-P-010	198	Fakih, FT	HPS-P-098	158
Djukic, Lj	CPS-P-044	110	Fakih, FT	HPS-P-099	158

Author Index

Author	Code	page	Author	Code	page
Falcao, AC	BB-P-017	195	Frisk, P	PI-P-020	184
Falcão, AC	HPS-P-065	150	Fröde, TS	CBS-P-007	99
Falcão, AC	LMCS-P-008	177	Fröde, TS	CBS-P-008	99
Fäldt, A	CPS-P-022	105	Fröde, TS	NS-P-014	199
Farias, M, dos S.	QP-P-016	213	Fröde, TS	NS-P-015	199
Faris, R	PI-O-005	189	Fröde, TS	NS-P-016	199
Fausto Ferreira, J	AS-O-008	95	Fröde, TS	NS-P-017	200
Fausto Ferreira, J	CPS-P-109	127	Frydenlund, B	CPS-P-034	108
Favre, M	CPS-P-084	120	Fuentes, M	CPS-P-017	104
Federman Neto, A	IPS-P-032	167	Fuentes, M	CPS-P-020	104
Feldborg Hansen, LFH	CPS-P-007	101	Fujii, M	BB-P-001	191
Fernandes, J	IPS-P-050	172	Fukuda, K	HPS-P-056	147
Fernandes, M	PI-P-021	185	Fukushima, SF	BB-P-002	191
Fernandes, R	CPS-P-101	125	Fuller, E	PB-P-006	204
Fernandes, R	HPS-P-087	155	Fuller, EJ	PB-P-006	204
Fernandes, RDC	CPS-P-089	122	Furukawa, H	HPS-P-020	138
Fernandes, RDC	HPS-P-094	157	Gadelha Carvalho, M	PI-P-018	184
Fernandez-Llimos, F	CPS-P-058	114	Gadelha Carvalho, M	PI-P-027	186
Ferracini, F	PI-P-015	183	Galindo Paes de Lira, RGP, de	BB-P-018	195
Ferrarini, M	BB-P-004	191	Gallani, N	PI-P-023	185
Ferreira, MMD	AS-P-005	92	Gallani, N	PP-P-013	208
Ferreira, MMD	AS-P-006	92	Gamba, M	IPS-P-013	163
Figueiredo, HF	CPS-P-091	122	Gambini, JP	NR-P-003	201
Figueiredo, IV	BB-P-017	195	Gameiro, T	LMCS-P-009	178
Figueiredo, IV	CPS-P-092	122	Ganieva, KhG	LMCS-P-002	176
Figueiredo, IV	NR-P-004	201	Garcias, G, de L.	QP-P-014	213
Figueiredo, IV	NR-P-005	202	Garcias, G, de L.	QP-P-017	214
Figueiredo, PM	PP-P-019	209	Gard, M	HPS-P-075	152
Figueiredo, PM	PP-P-020	209	Gard, M	HPS-P-076	152
Figueirinha, R	CPS-P-051	112	Gazikalovic, E	LMCS-P-005	177
Finizola, RM	HPS-P-100	158	Germain Noel, GN	BB-P-009	193
Fiqueira, ME	IPS-O-004	173	Gertrudes, V	CPS-P-092	122
Fleitas, S	CPS-P-110	127	Gerzso, FBM	CPS-P-123	130
Florêncio de Melo, JC	PI-P-018	184	Gharat, MS	ABS G05-3	55
Florencio Neves, AC	HPS-P-085	155	Gharat, MS	BIO G05-3	53
Florio, JC	CBS-P-002	98	Gharat, MS	CPS-P-114	128
Fonseca, IA	IPS-P-041	170	Gharib, S	PP-P-010	207
Fontana, D	CPS-P-016	103	Gherardi, A	CPS-P-110	127
Fontana, MC	IPS-P-034	168	Ghous, M	PI-P-001	180
Fonteles, M	AS-P-007	92	Ghous, Z	HPS-P-046	145
Fonteles, M	HPS-P-063	149	Gilissen, M	PI-P-009	182
Formiga, F	IPS-P-040	169	Gimenes, FRE	HPS-P-098	158
Formiga, F	IPS-P-041	170	Gimenes, FRE	HPS-P-101	159
Forrey, R	HPS-P-086	155	Girerd, X	CPS-P-002	100
Fortuit, P	CPS-P-031	107	Glenn, D	HPS-P-009	136
Fortuit, P	CPS-P-087	121	Godinho, I	LMCS-P-008	177
Fortuit, P	HP-O	133	Goebel, K	QP-P-012	212
Frade, J	CPS-P-058	114	Gomaa, Y	IPS-O-001	173
Fraga Santana, V	QP-P-001	210	Gomes, AS	IPS-P-031	167
Fraga Santana, V	QP-P-002	210	Gomes, DF	PP-P-002	205
Franca, GG	HPS-P-027	140	Gomez, RG	APS-P-002	96
Francula, IF	HPS-P-049	146	Gomita, Y	BIO R2-6	3
Francula, IF	HPS-P-050	146	Gomita, YG	ABS R2-6	5
Franzén, BIM	CPS-P-063	115	Gonçalves, E	HPS-P-053	147
Freire de Sousa, D	HPS-P-089	156	Goncalves, JC	BB-P-007	192
Freitas Dias, M	BIO R1-0	1	Goncalves, JC	BB-P-008	192
Fresco, P	NS-P-010	198	Goncalves, JC	BB-P-009	193
Friedrich, RB	IPS-P-034	168	Gonçalves, JG	AS-P-001	91

Author Index

Author	Code	page	Author	Code	page
Gonçalves, LPB	IPS-P-039	169	Hartman, NG	BIO S6-2	32
Gonçalves, RG	ABS P3-1	12	Hashim, R	BB-P-006	192
Gonçalves, RG	BIO P3-1	11	Haugbølle, LS	CPS-P-125	131
González Gutierrez, D	QP-P-001	210	Haugbølle, LSH	AS-O-007	95
Goodyer, LI	PI-O-002	188	Haugbølle, LSH	PI-P-010	182
Goretti R. de Queiroz, M	HPS-P-089	156	Hayakawa, TH	BB-P-002	191
Goto, NG	BB-P-002	191	Haznar, D	BB-P-012	193
Goulart, MA	PP-P-003	205	He, J	QP-P-007	211
Goulart, S	NS-P-014	199	Hemming, M	PI-O-001	188
Goulart, S	NS-P-015	199	Heras, MI	HPS-P-074	152
Goulart, S	NS-P-016	199	Herborg, H	CPS-P-028	106
Gourley, D	PI-O-005	189	Herborg, HH	ABS P3-2	12
Gourley, DG	CPS-P-012	102	Herborg, HH	BIO P3-2	11
Gourley, G	PI-O-005	189	Hernández-León, L	IPS-P-001	160
Granaas, AG	CPS-P-080	119	Hernández-León, L	IPS-P-004	160
Grandi, T	CBS-P-005	99	Herradón, J	CPS-P-017	104
Grandia, L	CPS-P-090	122	Herradón, J	CPS-P-020	104
Grandia, L	PI-O-007	189	Higashi, M	ABS G24	89
Gray, AL	BIO G17-0	72	Hiljadnikova-Bajro, H	HPS-P-083	154
Grbic, S	HP-P-002	130	Hilmann, MCR	NS-P-017	200
Green, KG	IPS-O-011	175	Hioka, N	IM-P-001	215
Gregoire, J-P	ABS G06	58	Hirano, M	AS-P-009	93
Gregoire, J-P	ABS G11-2	65	Hocherg, G	PI-P-005	181
Gregoire, J-P	BIO G06	57	Hocherg, G	PI-P-006	181
Gregoire, J-P	BIO G11-2	63	Hodson, K	AS-O-006	95
Grimshaw, E	IM-P-001	215	Holland, RW	BIO R2-7	3
Grønfeldt, A	CPS-P-014	103	Holland, W	ABS G02-3	48
Grosek, L	CPS-P-094	123	Holland, W	BIO G02-3	46
Groves, S	ABS G24	89	Holloway, KA	ABS G22-4	87
Grundler, A	CPS-P-102	125	Holloway, KA	BIO G22-3	86
Gruvmalm, A	CPS-P-098	124	Holme Hansen, E	PI-O-006	189
Guedes, LFP	PI-P-029	187	Honda, AM	BB-P-004	191
Gueira Júnior, AA	CPS-P-003	100	Honda, TH	ABS S4-2	29
Gulati, I	IPS-P-017	164	Honda, TH	BIO S4-2	28
Guo, T	QP-P-007	211	Hong, M	CPS-P-018	104
Gurgel, A	HPS-P-030	141	Horn, AM	CPS-P-080	119
Guterres, SS	IPS-P-034	168	Hostettmann, KH	ABS S4-3	29
Guzzo, GCG	AS-P-005	92	Hostettmann, KH	BIO S4-3	28
Guzzo, GCG	AS-P-006	92	Hrnjic, HM	PP-P-006	206
Haemmerlein, A	CPS-P-059	114	Hrnjic, M	HPS-P-010	136
Hagman, M	CPS-P-057	114	Hsiao, F	CPS-P-074	118
Hakkarainen, KME	ABS G15-1	70	Hsiao, F	CPS-P-075	118
Hakkarainen, KME	BIO G01-0	43	Hsiao, F	IPS-P-029	167
Hakkarainen, KME	BIO G15-0	68	Hsiao, F	PI-P-008	181
Halmos, GH	CPS-P-012	102	Hsieh, CF	IPS-P-029	167
Hamada, K	HPS-P-056	147	Hsieh, DY	HPS-P-022	139
Han, H-H	IPS-P-008	161	Hsieh, MC	CBS-P-003	98
Han, H-H	IPS-P-025	166	Hsieh, MC	CBS-P-004	98
Han, H-H	IPS-P-026	166	Hsieh, MC	CPS-P-064	115
Han, M-J	IPS-P-008	161	Hsieh, Y	HPS-P-064	149
Han, M-J	IPS-P-026	166	Hsieh, YW	HPS-P-035	142
Hansen, TS	CPS-P-024	105	Hsu, AT	CPS-P-074	118
Han-ya, M	AS-P-009	93	Hsu, AT	CPS-P-075	118
Harada, K	HPS-P-056	147	Hsu, CS	HPS-P-062	149
Harai, S	HPS-P-082	154	Hsu, HY	CPS-P-064	115
Harrison, J	AS-P-007	92	Hsu, HY	CPS-P-096	123
Hartman, NG	ABS S6-01	35	Hsu, MLH	HPS-P-016	137
Hartman, NG	ABS S6-08	37	Hu, JM	LMCS-P-006	177

Author Index

Author	Code	page	Author	Code	page
Huang, WF	IPS-P-029	167	Kaarill, LK	CPS-P-045	111
Huang, WF	PI-P-008	181	Kallesen, M	CPS-P-108	126
Huang, YC	HPS-P-062	149	Kamei, H	AS-P-009	93
Huang, YT	PI-P-008	181	Kamel, OK	IPS-O-005	174
Huang, ZK	CPS-P-077	119	Kaneko, TM	BB-P-004	191
Hudson, S	ABS P2-4	9	Kaneko, TM	BB-P-004	191
Hudson, S	BIO P2-3	8	Kaneko, TM	IPS-O-006	174
Hue wu, W	CPS-P-073	118	Kanfer, I	NS-P-004	196
Hung, C	HPS-P-078	153	Kanjanarat, P	CPS-P-113	128
Hung, YJ	HPS-P-038	143	Kao Yang, YH	HPS-P-038	143
Hung, YJ	HPS-P-045	145	Kao Yang, YH	HPS-P-044	144
Hurtado, FK	QP-P-011	212	Kao Yang, YH	HPS-P-045	145
Hussaini, M	CPS-P-015	103	Kao, SJK	HPS-P-016	137
Hussaini, M	NS-P-003	196	Kao, YW	HPS-P-079	153
Hyldig, CH	ABS G21-4	84	Kapadanovska, K	HPS-P-083	154
Hyldig, CH	BIO G21-5	83	Kapadia, S	AS-O-003	94
Ibekwe, CM	HPS-P-018	138	Kapoor, N	IPS-P-016	163
Ibekwe, CM	HPS-P-019	138	Karolewicz, B	BB-P-013	194
Imai, SI	BB-P-002	191	Kauki, TM	HPS-P-001	134
Inotsume, I	BB-P-002	191	Kaur, S	PI-O-004	188
Isawa, M	PI-P-002	180	Kawamura, K	CPS-P-119	129
Issarangkuin na Ayuthaya, A	CPS-P-112	127	Keitel, S	BIO PS2-0	18
Ivama, AMI	ABS P4-2	15	Keitel, S	BIO S8	41
Ivama, AMI	BIO P4-2	13	Keskintepe, DK	NR-P-001	201
Ivanovic, G	HPS-P-002	134	Keskintepe, DK	NR-P-002	201
Ivey, F	ABS P2-6	10	Khalidi, N	HPS-P-024	139
Ivey, F	BIO G17-2	72	Khanavi, M	NS-P-002	196
Iwamoto, S	HPS-P-042	144	Khandavilli, S	IPS-P-014	163
Izumikubo, AI	HPS-P-039	143	Khandavilli, S	IPS-P-022	165
Jacobsgaard, H	CPS-P-045	111	Kheir, N	AS-P-007	92
Jacobsgaard, HJ	ABS G20-2	81	Kheir, N	HPS-P-063	149
Jacobsgaard, HJ	BIO G20-2	80	Kido, M	CPS-P-119	129
Jalundhwala, YJJ	ABS G05-4	55	Kikuchi, IS	HPS-P-077	153
Jalundhwala, YJJ	BIO G05-4	53	Kikuchi, IS	IPS-O-003	173
Jambrek, JN	PP-P-009	207	Kim, CK	BB-P-016	194
Jang, M	CPS-P-018	104	Kim, CK	PB-P-005	204
Jednak Jovanovic, N	CPS-P-044	110	Kim, J-A	IPS-O-007	174
Jensen, H	CPS-P-040	109	Kim, J-A	IPS-P-007	161
Jeppesen, B	CPS-P-014	103	Kim, J-A	IPS-P-008	161
Jevric-Causevic, A	CBS-P-006	99	Kim, J-A	IPS-P-009	162
Ji, M	HPS-P-103	159	Kim, J-A	IPS-P-010	162
Jiang, RL	HPS-P-035	142	Kim, J-A	IPS-P-024	165
Jiang, Y	AS-O-002	94	Kim, J-A	IPS-P-025	166
Jiang, YH	PI-P-013	183	Kim, J-A	IPS-P-026	166
Jiang, YM	CPS-P-096	123	Kim, J-A	IPS-P-027	166
Jiang, YS	PI-P-013	183	Kim, J-A	IPS-P-028	166
Jin, SHJ	ABS PS2-2	20	Kimura, M	HPS-P-082	154
Jin, SHJ	BIO PS2-2	18	Kishimoto, SK	BB-P-002	191
Joda, A	CPS-P-117	129	Kitikannakorn, N	PI-P-014	183
Joda, A	CPS-P-118	129	Kjær, IMK	CPS-P-039	109
Jönsson, B	ABS P4-1	15	Kleinebreil, L	PI-P-005	181
Jönsson, B	BIO P4-1	13	Kleinebreil, L	PI-P-006	181
Joshi, S	PI-O-004	188	Ko, WC	HPS-P-044	144
Josifovski, J	HPS-P-083	154	Kocic Pesic, V	CPS-P-048	111
Juillet, YJ	ABS G10-1	62	Kocic Pesic, V	CPS-P-048	111
Juillet, YJ	BIO G10-1	61	Kocic Pesic, V	CPS-P-067	116
Jukic, M	CPS-P-060	114	Kodaka, M	ABS G24	89
Kaakeh, Y	HPS-P-009	136	Koga, NK	HPS-P-039	143

Author Index

Author	Code	page	Author	Code	page
Koichi Kawasaki,	ABS G22-5	88	Lang, KL	NS-P-016	199
Kondo, NK	HPS-P-039	143	Lara-Hernández, H	IPS-P-004	160
Kondoh, M	BB-P-001	191	Larsen, AB	CPS-P-125	131
Konishi, T	BB-P-005	192	Larsen, HL	CPS-P-007	101
Koraiem, YK	BIO G15-0	68	Larsen, M	CPS-P-027	106
Kose, N	PI-P-002	180	Lautridou, R	HPS-P-061	149
Kovacevic, N	CPS-P-013	103	Layloff, P	ABS PS2-1	20
Kovacevic, N	NS-P-008	197	Layloff, P	BIO PS2-1	18
Krähenbühl, J-M	CPS-P-083	120	Leal Bastos da Silva, LLB, da	BB-P-019	195
Kravzov Jinich, J	APS-P-007	97	Leal, M	CPS-P-092	122
Kravzov-Jinich, JKJ	ABS G10-3	62	Lee, CH	HPS-P-068	150
Kravzov-Jinich, JKJ	APS-P-002	96	Lee, IH	HPS-P-038	143
Kravzov-Jinich, JKJ	BIO G10-3	61	Lee, IH	HPS-P-045	145
Kristiansen, JK	CPS-P-029	107	Lee, L	HPS-P-047	145
Kristinsson, KG	PI-O-006	189	Lee, PY	HPS-P-060	148
Kristoffersen, L	CPS-P-069	117	Lee, SP	CPS-P-077	119
Krug, LP	CBS-P-005	99	Lee, WC	HPS-P-066	150
Krydsfeldt, M	CPS-P-040	109	Lee, Z	HPS-P-060	148
Kubis, A	BB-P-010	193	Lefevre, D	CPS-P-087	121
Kubis, A	BB-P-011	193	Lehr, C-M	ABS P1-2	7
Kubis, AA	BB-P-010	193	Lehr, C-M	BIO P1-2	6
Kubis, AA	BB-P-011	193	Leitão, F	HPS-P-065	150
Kubota, A	HPS-P-042	144	Leitão, F	LMCS-P-008	177
Kubota, AK	HPS-P-039	143	Lelie-van der Zande, R	CPS-P-090	122
Kujundzic, M	HP-P-001	130	Lelie-van der Zande, R	PI-O-007	189
Kujundzic, N	HP-P-001	130	Lelie-van der Zande, R	PI-P-009	182
Kulkarni, TP	CBS-P-001	98	Lepage, H	PI-P-005	181
Kuo, CJ	APS-P-004	96	Lepage, H	PI-P-006	181
Kurosawa, N	AS-P-008	92	Letanoux, M	PI-P-005	181
Kwak, M-K	IPS-O-007	174	Letanoux, M	PI-P-006	181
Kwak, M-K	IPS-P-007	161	Leufkens, G	ABS G21-1	84
Kwak, M-K	IPS-P-008	161	Leufkens, G	ABS S7	40
Kwak, M-K	IPS-P-009	162	Leufkens, G	BIO G21-1	82
Kwak, M-K	IPS-P-010	162	Leufkens, G	BIO S7	39
Kwak, M-K	IPS-P-024	165	Lewis, A	BIO G04-1	50
Kwak, M-K	IPS-P-025	166	Li, D-X	IPS-O-007	174
Kwak, M-K	IPS-P-026	166	Li, D-X	IPS-P-009	162
Kwak, M-K	IPS-P-027	166	Li, D-X	IPS-P-024	165
Kwak, M-K	IPS-P-028	166	Li, D-X	IPS-P-027	166
Kwon, R	IPS-P-007	161	Li, D-X	IPS-P-028	166
Kwon, R	IPS-P-025	166	Li, J	AS-P-005	92
Lacour-Candiard, K	CPS-P-001	100	Li, J	AS-P-006	92
Lacour-Candiard, K	CPS-P-002	100	Liao, SC	IPS-P-030	167
Ladavac, M	CPS-P-060	114	Lien, JM	CPS-P-064	115
Lai, HS	HPS-P-022	139	Lien, JM	CPS-P-096	123
Lai, L	PP-P-010	207	Lien, JM	HPS-P-022	139
Lai, MC	CPS-P-077	119	Lima, LG	IPS-P-036	168
Lai, YY	CBS-P-004	98	Lima, LG	IPS-P-037	169
Lalej, D	PI-P-005	181	Lima, LG	IPS-P-038	169
Lalej, D	PI-P-006	181	Lima, MF	HPS-P-027	140
Lallement, G	MEPS-P-001	179	Lin, CFL	HPS-P-016	137
Lambertini, NR	CPS-P-070	117	Lin, CJ	NS-P-006	197
Lambertini, NR	CPS-P-071	117	Lin, CJ	PI-P-013	183
Lan, TH	CPS-P-077	119	Lin, FY	HPS-P-022	139
Lanao, JM	HPS-P-074	152	Lin, LJ	HPS-P-022	139
Landsgrav, L	CPS-P-036	108	Lin, MF	HPS-P-043	144
Lang, KL	NS-P-014	199	Lin, MF	HPS-P-044	144
Lang, KL	NS-P-015	199	Lin, MT	HPS-P-022	139

Author Index

Author	Code	page	Author	Code	page
Lin, TH	CBS-P-003	98	Machado, MS	HPS-P-055	147
Lin, XR	PI-P-013	183	MacKinnon, J	ABS R2-2	4
Lin, YM	HPS-P-062	149	MacKinnon, J	BIO R2-2	2
Lin, Y-M	HPS-P-067	150	Madhusudan Rao, Y	IPS-P-011	162
Linaza, I	CPS-P-017	104	Maeda, M	ABS G22-5	88
Linaza, I	CPS-P-020	104	Maejima, D	BB-P-005	192
Lindhe-Söderlund, L	CPS-P-052	112	Magalhães Ferreira, J	HPS-P-089	156
Liou, W	HPS-P-047	145	Mahieddine, F	CPS-P-087	121
Liou, W	HPS-P-104	159	Maia, M	HPS-P-091	156
Liou, WS	HPS-P-052	146	Majstorovic, Lj	CPS-P-060	114
Liou, WS	HPS-P-081	154	Makady, SAM	IPS-O-010	175
Liou, WS	PI-P-026	186	Makino, M	HPS-P-042	144
Lira, AAM	IPS-P-032	167	Makishima, T	ABS G24	89
Liu Yeh, PY	HPS-P-021	139	Malcic, S	QP-P-009	212
Liu, H-J	HPS-P-058	148	Malenica, M	CBS-P-006	99
Liu, JW	HPS-P-040	143	Malmqvist, S	CPS-P-097	124
Liu, MH	CPS-P-074	118	Manfio, J	BB-P-015	194
Liu, MH	IPS-P-030	167	Manfio, J	QP-P-008	211
Llimós, F	PI-P-021	185	Manfio, JL	QP-P-012	212
Locca, JF	CPS-P-084	120	Manfio, JM	BB-P-015	194
Loebenberg, R	NS-P-007	197	Manfio, JM	QP-P-008	211
Lombardo, F	PI-P-012	182	Mano, A	LMCS-P-008	177
Lopes, MC	NR-P-004	201	Mansano, RD	IPS-P-002	160
Lourenço, FRL	QP-P-003	210	Marais, AF	IPS-P-012	162
Lu, KH	LMCS-P-006	177	Maraslis, FT	NS-P-017	200
Lu, MS	HPS-P-052	146	Marchetti, JM	IPS-P-032	167
Luinenburg, J	PI-P-009	182	Marciniak, DM	BB-P-010	193
Luis Menezes Carvalho, ALMC	BB-P-020	195	Marciniak, DM	BB-P-011	193
Lundahl, H	CPS-P-076	118	Maria Costa Martins, A	HPS-P-089	156
Luppi Jr., P	HPS-P-004	134	Marinho, JT	PP-P-002	205
Luscombe, D	AS-O-006	95	Marklund, B	CPS-P-022	105
Lütz, L-K	CPS-P-076	118	Markovic Pekovic, V	APS-P-001	96
Lutz, M	ABS G18-5	78	Marques, AC	NR-P-005	202
Lutz, M	BIO G18-4	76	Marques, DR	HPS-P-096	157
Lyftingsmo, S	HPS-P-017	138	Marques, TC	CPS-P-070	117
Lyoo, WS	IPS-O-007	174	Marques, TC	CPS-P-071	117
Lyoo, WS	IPS-P-007	161	Marriott, JL	ABS G01-3	45
Lyoo, WS	IPS-P-008	161	Marriott, JL	ABS G17-1	74
Lyoo, WS	IPS-P-009	162	Marriott, JL	BIO G01-3	44
Lyoo, WS	IPS-P-010	162	Marriott, JL	BIO G17-1	72
Lyoo, WS	IPS-P-024	165	Martiarena, J	PI-P-012	182
Lyoo, WS	IPS-P-025	166	Martiarena, JL	PB-P-004	203
Lyoo, WS	IPS-P-026	166	Martin, JE	ABS G21-5	85
Lyoo, WS	IPS-P-027	166	Martin, JE	BIO G21-6	83
Lyoo, WS	IPS-P-028	166	Martinello, T	IPS-O-006	174
Lyra Jr., DP	CPS-P-070	117	Martinez C. de Cerqueira, RM	CPS-P-101	125
Lyra Jr., DP	CPS-P-071	117	Martinez C. de Cerqueira, RM	CPS-P-104	125
Lyra Jr., LP	CPS-P-035	108	Martinez C. de Cerqueira, RM	CPS-P-105	126
Lyra Júnior, DP	HPS-P-098	158	Martinez C. de Cerqueira, RM	CPS-P-107	126
Lyra Júnior, DP	HPS-P-099	158	Martinez C. de Cerqueira, RM	HPS-P-087	155
Lyra Júnior, DP	HPS-P-101	159	Martins, IM	MEPS-P-004	179
M Lanao, J	HPS-P-074	152	Martins, R	HPS-P-053	147
Ma, J	ABS G24	89	Martins, R	HPS-P-054	147
Ma, J	MEPS-P-002	179	Martins, R	HPS-P-055	147
Ma, L	BB-P-003	191	Martins, R	HPS-P-091	156
Macedo, LS	HPS-P-092	156	Martins, R	HPS-P-092	156
Macedo, TA	NR-P-004	201	Martins, R	PI-P-019	184
Machado, MOB	HPS-P-055	147	Martin-Suarez, A	HPS-P-074	152

Author Index

Author	Code	page	Author	Code	page
Maruyama, Y	ABS G24	89	Miranda, AP	HPS-P-053	147
Mascarenha, K	HPS-P-092	156	Mirkov, S	HPS-P-063	149
Matos, FD	APS-P-008	97	Mirkovic, DM	HPS-P-031	141
Matos, FD	CPS-P-100	124	Mirkovic, DM	HPS-P-032	141
Matos, GC	PP-P-012	207	Mitchell, J	HPS-P-009	136
Matos, GC	PP-P-012	207	Moffat, AC	BIO PS2-3	19
Matsuba, K	AS-P-009	93	Moghimipour, E	NS-P-007	197
Matsui, E	ABS G24	89	Mohamed, N	PB-P-001	203
Matuo, MCS	IPS-O-003	173	Mohammed, JL	PB-P-001	203
M'Bemba, J	PI-P-005	181	Mohammed, M	CPS-P-006	101
M'Bemba, J	PI-P-006	181	Mohammed, M	CPS-P-015	103
McAllister, R	HPS-P-011	136	Mohammed, M	NS-P-003	196
McAllister, R	HPS-P-013	137	Mohammed, M	PB-P-001	203
McClure, L	ABS G20-1	81	Mohammed, M	PB-P-001	203
McClure, L	BIO G20-1	79	Moles, RJ	ABS R2-4	4
McCormick, R	CPS-P-025	106	Moles, RJ	BIO G04-0	50
McCormick, R	CPS-P-026	106	Moles, RJ	BIO R2-4	2
McDevitt, L	BIO G04-0	50	Moles, RJ	HPS-P-008	135
McDevitt, L	BIO G21-0	82	Monks, LF	QP-P-017	214
McElnay, JC	ABS R2-3	4	Mønster, J	CPS-P-124	130
McElnay, JC	BIO R2-3	2	Monteira Alvim, M	CPS-P-082	120
McEvoy, K	ABS G09-3	60	Morais, CE	PI-P-029	187
McKinney, R	HPS-P-011	136	Morais, LB	CPS-P-003	100
McKinney, R	HPS-P-013	137	Moreira, AJ	IPS-P-002	160
Medeiros, A	IPS-P-042	170	Moreira, AR	ABS S3-1	27
Medeiros, FPM	IPS-P-038	169	Morgadinho, TR	NR-P-005	202
Meek, W	CPS-P-066	116	Morimoto, Y	HPS-P-082	154
Mehta, A	ABS S1	22	Moritz, MIG	NS-P-014	199
Mehta, A	BIO S1	21	Moritz, MIG	NS-P-015	199
Melo, JRR	PP-P-019	209	Moritz, MIG	NS-P-016	199
Melo, JRR	PP-P-020	209	Moriuchi, H	MEPS-P-003	179
Mendes-Oustric, A-C	MEPS-P-001	179	Mosnier-Pudar, H	PI-P-005	181
Mendonça, JS	IPS-P-039	169	Mosnier-Pudar, H	PI-P-006	181
Menezes, AP	CPS-P-120	129	Mota Gonçalves, TMG	BB-P-018	195
Menezes, AP	PI-P-028	186	Mota Gonçalves, TMG	BB-P-019	195
Menezes, AP	PP-P-016	208	Mota Gonçalves, TMG	BB-P-020	195
MERIC, A	IPS-P-033	168	Mott, G	BIO G09-2	59
Mesa, JA	HPS-P-074	152	Moura, A	PI-P-018	184
Meštrovic, A	CPS-P-102	125	Moura, A	PI-P-027	186
Meyer, TA	HPS-P-011	136	Moura, MLO	PP-P-012	207
Meyer, TA	HPS-P-013	137	Mueller, U	CPS-P-059	114
Miasso, AI	HPS-P-098	158	Mulabegovic, MN	PP-P-006	206
Miasso, AI	HPS-P-099	158	Murbach, P	CPS-P-099	124
Miasso, AI	HPS-P-101	159	Muttaqi, S	PI-P-001	180
Midha, K	ABS S2-4	25	Nagashima, T	IPS-P-043	170
Midha, K	BIO S2-4	24	Nagashima, T	IPS-P-044	170
Migotto, RAR	HPS-P-030	141	Naidu, M	CPS-P-056	113
Mihajlovic, G	PI-P-003	180	Naidu, M	HPS-P-034	142
Mihajlovic, I	PI-P-003	180	Naidu, M	HPS-P-036	142
Milic, J	CPS-P-013	103	Nakashima, E	PI-P-002	180
Milic, J	IPS-P-035	168	Nanaumi, Y	CPS-P-115	128
Miljkovic, B	HPS-P-002	134	Nanaumi, Y	CPS-P-116	128
Miller, DA	IPS-P-013	163	Nanaumi, Y	PI-P-022	185
Milosevic, D	CPS-P-106	126	Nanclares, DMA	IPS-P-032	167
Milosevic-Kostadinovic, K	CPS-P-106	126	Nazário, A	CPS-P-089	122
Milosevic-Kostadinovic, K	CPS-P-047	111	Neeraj Kumar, M	IPS-P-023	165
Milosevic-Kostadinovic, K	HP-P-002	130	Negreiros, RL	PP-P-012	207
Mineo, S	BB-P-005	192	Nervo Raffin, F	PI-P-027	186

Author Index

Author	Code	page	Author	Code	page
Neves de Miranda, NM	BB-P-007	192	Oliveira, A	HPS-P-094	157
Neves de Miranda, NM	BB-P-008	192	Oliveira, C, de	LMCS-P-008	177
Neves de Miranda, NM	BB-P-009	193	Oliveira, D	IPS-P-002	160
Newa, M	IPS-O-007	174	Oliveira, DC	QP-P-011	212
Newa, M	IPS-P-010	162	Oliveira, E	IPS-P-050	172
Newa, M	IPS-P-024	165	Oliveira, JC	PP-P-012	207
Newa, M	IPS-P-026	166	Oliveira, MA	PI-P-030	187
Newa, M	IPS-P-028	166	Oliveira, MGG, de	PP-P-014	208
Nguyen, P	AS-P-005	92	Oliveira, PCR, de	CPS-P-003	100
Nguyen, P	AS-P-006	92	Oliveira, RC	HPS-P-098	158
Ni, M	BB-P-003	191	Oliveira, RC	HPS-P-099	158
Nicholson, MJN	ABS G21-3	84	Olsen, V	CPS-P-014	103
Nicholson, MJN	ABS PS1-2	17	Ooi, K	HPS-P-082	154
Nicholson, MJN	BIO G21-3	82	Orii, T	HPS-P-029	141
Nicholson, MJN	BIO PS1-2	16	Orsonez, N	IPS-P-002	160
Niel, C	CBS-P-005	99	Oshiro, ML	PP-P-011	207
Nielsen, S	CPS-P-053	113	Osório-de-Castro, CGS	PP-P-012	207
Nikolic, A	PB-P-003	203	Otonicar, N	CPS-P-010	102
Nilsson, L	CPS-P-022	105	Özdemir, C	CPS-P-052	112
Nimmo, M	ABS G02-4	48	Ozer, AY	ABS S6-03	35
Nimmo, M	BIO G02-4	46	Ozer, AY	BIO S6-4	33
Niquille, A	CPS-P-054	113	Ozer, AY	NR-P-001	201
Niquille, A	CPS-P-083	120	Ozer, AY	NR-P-002	201
Niu, W	QP-P-005	211	Ozer, AY	NR-P-002	201
Noal, C	HPS-P-102	159	Pacheco, F	CPS-P-104	125
Noblat, ACB	PP-P-014	208	Pacheco, F	CPS-P-105	126
Noblat, L	PP-P-014	208	Pacheco, F	CPS-P-107	126
NOBLAT, LAC	CPS-P-062	115	Pacheco, MP	CPS-P-062	115
Nogueira, AM	PI-P-021	185	Pacheco, MP	CPS-P-072	117
Nogueira, AM	PI-P-021	185	Pacheco, MP	HPS-P-091	156
Nonkovic, Z	HPS-P-025	140	Pacheco, MP	HPS-P-092	156
Nordén-Hagg, A	CPS-P-046	111	Pacheco, MP	PI-P-019	184
Nordmark, B	PI-P-016	183	Pacholsk, I	QP-P-017	214
Nordqvist, M	CPS-P-032	107	Padovani, MC	PP-P-002	205
Norelius, M	CPS-P-052	112	Padovani, MC	PP-P-003	205
Norelius, M	CPS-P-057	114	Panchagnula, R	IPS-P-014	163
Novakova, L	IPS-O-002	173	Panchagnula, R	IPS-P-015	163
Nováková, L	LMCS-P-009	178	Panchagnula, R	IPS-P-016	163
Novovic, Z	CPS-P-044	110	Panchagnula, R	IPS-P-017	164
Numphanon, H	CPS-P-112	127	Panchagnula, R	IPS-P-018	164
Nunes, SF	NR-P-004	201	Panchagnula, R	IPS-P-019	164
Nunes, SF	NR-P-005	202	Panchagnula, R	IPS-P-020	164
Nwoke, O	CPS-P-117	129	Panchagnula, R	IPS-P-021	165
Nylander, E	CPS-P-078	119	Panchagnula, R	IPS-P-022	165
Obono, MO	HPS-P-018	138	Panchagnula, R	IPS-P-023	165
Oda, LM	ABS S3-3	27	Pangersic, B	CPS-P-094	123
Oda, LM	BIO S3	26	Panovski, P	HPS-P-083	154
Øding, L	CPS-P-014	103	Paolino, A	NR-P-006	202
Odin-Liljedahl, K	CPS-P-097	124	Paraje, MG	CPS-P-103	125
Ofoefule, SI	IPS-P-003	160	Paresys-Barbier, J	CPS-P-087	121
Oh, D-H	IPS-P-008	161	Park, J-K	IPS-P-007	161
Oh, D-H	IPS-P-026	166	Park, J-K	IPS-P-025	166
Oh, D-H	IPS-P-027	166	Park, J-K	IPS-P-027	166
Ohman, S	AS-P-004	91	Parker, J	ABS G09-4	60
Okada, H	CPS-P-119	129	Parker, J	BIO G09-4	59
Okada, S	IPS-P-006	161	Parojcic, D	CPS-P-047	111
Oliveira Melo, D	PP-P-015	208	Parojcic, D	CPS-P-047	111
Oliveira, A	CPS-P-089	122	Parojcic, D	CPS-P-106	126

Author Index

Author	Code	page	Author	Code	page
Parojcic, D	HP-O	133	Piao, M-G	IPS-P-028	166
Parojcic, D	HP-O	133	Pinto, TJA	HPS-P-077	153
Parojcic, D	HP-P-002	130	Pinto, TJA	IPS-O-003	173
Parojcic, D	HP-P-002	130	Pinto, TJA	IPS-P-002	160
Pasalic, Dz	CBS-P-006	99	Pinto, TJA	QP-P-003	210
Pasko, D	HPS-P-009	136	Pires de Abreu, LRP, de	BB-P-018	195
Passos, LC	PP-P-014	208	Pires de Abreu, LRP, de	BB-P-019	195
Patnala, S	NS-P-004	196	Piuma, L	NR-P-003	201
Paulino, E	ABS G05-2	55	Piuma, L	NR-P-006	202
Paulino, E	BIO G05-2	53	Pluta, J	BB-P-012	193
Paulino, E	BIO G20-0	79	Pluta, J	BB-P-013	194
Paulo, PTC	HPS-P-096	157	Pocuca, M	HP-P-003	130
Paulo, PTC	HPS-P-097	158	Pohlmann, AR	IPS-P-034	168
Paulo, PTC	HPS-P-097	158	Pokrajac, M	HPS-P-002	134
Paulo, PTC	HPS-P-100	158	Polli, JE	ABS S2-3	25
Paulo, PTC	HPS-P-100	158	Polli, JE	BIO S2-3	23
Paulus, PA	ABS S8	42	Ponciano, E	CPS-P-051	112
Paulus, PA	BIO S8	41	Popovic, M	CPS-P-044	110
Pavlovic, L	CPS-P-086	121	Portela, AS	HPS-P-097	158
Pedersen, KP	CPS-P-045	111	Postel-Vinay, N	CPS-P-002	100
Pedraz, C	HPS-P-074	152	Power, B	CPS-P-066	116
Pedro Antunes, F	NS-P-010	198	Previdello, BAF	IM-P-001	215
Pedro, S	HPS-P-089	156	Pugens, AM	BB-P-015	194
Pedroso, P	AS-O-008	95	Pugens, AM	QP-P-008	211
Pedroso, P	CPS-P-109	127	Pumtong, S	CPS-P-008	101
Pelá, IR	CPS-P-035	108	Pumtong, S	CPS-P-009	102
Pelá, IR	CPS-P-070	117	Pupacic, VP	HPS-P-049	146
Pelá, IR	CPS-P-071	117	Pupacic, VP	HPS-P-050	146
Peloi, LS	IM-P-001	215	Purvis, TP	IPS-P-013	163
Pena, A	LMCS-P-009	178	Putic, VP	HPS-P-031	141
Peña, C	CPS-P-017	104	Putic, VP	HPS-P-032	141
Peña, C	CPS-P-020	104	Puumalainen, II	ABS G15-3	70
Pena, MJLP	APS-P-003	96	Qiu, YL	CPS-P-096	123
Pereira de Santana, D	BB-P-018	195	Qu, B	AS-P-005	92
Pereira de Santana, D	BB-P-019	195	Qu, B	AS-P-006	92
Pereira de Santana, D	BB-P-020	195	Queiroz, APP	CPS-P-072	117
Pereira, C	CPS-P-104	125	Quirino, CT	AS-P-002	91
Pereira, C	CPS-P-105	126	Rabelo, A	HPS-P-053	147
Pereira, C	CPS-P-107	126	Radonjic, V	PI-P-007	181
Pereira, RR	CBS-P-008	99	Radonjic, V	PI-P-024	185
Pérez Rojas, A	QP-P-001	210	Radonjic, V	PI-P-024	185
Peric, A	PI-P-004	180	Radonjic, V	PI-P-025	186
Peric, A	PP-P-004	205	Radonjic, V	PI-P-025	186
Peric, B	HP-O	133	Rajab, MH	HPS-P-011	136
Perumal, OP	IPS-P-015	163	Rajab, MH	HPS-P-013	137
Perumal, OP	IPS-P-019	164	Ramazani, M	NS-P-007	197
Peschardt, B	CPS-P-014	103	Ramnik Singh, S	IPS-P-021	165
Peter, J	HPS-P-012	136	Ramos, AB	CBS-P-005	99
Peter, J	HPS-P-014	137	Ramos, F	AS-O-008	95
Petronijevic, D	HPS-P-002	134	Ramos, F	CPS-P-109	127
Petronijevic, M	HPS-P-002	134	Ramos, S	IPS-P-036	168
Petrovic, S	IPS-P-035	168	Ramos, S	IPS-P-037	169
Phan, H	HPS-P-009	136	Ramos, S	IPS-P-038	169
Phanouvong, SP	ABS S8	42	Ramos, SVV	IPS-P-038	169
Piao, M-G	IPS-O-007	174	Rangel da Silva Filho, J	PI-P-018	184
Piao, M-G	IPS-P-009	162	Ravera, E	CPS-P-110	127
Piao, M-G	IPS-P-024	165	Raw, ASR	ABS S8	42
Piao, M-G	IPS-P-027	166	Raw, ASR	BIO S8	41

Author Index

Author	Code	page	Author	Code	page
Rawat, M	PB-P-002	203	Rosado, VR	PP-P-003	205
Raynor, DK	ABS G09-1	60	Rosovic-Bazijanac, V	HPS-P-048	145
Raynor, DK	ABS G18-3	77	Rosovic-Bazijanac, V	HPS-P-049	146
Raynor, DK	BIO G09-1	59	Rosovic-Bazijanac, V	HPS-P-050	146
Raynor, DK	BIO G18-3	75	Rosovic-Bazijanac, V	HPS-P-051	146
Raza, S	PI-O-009	190	Rossetti, MLR	CBS-P-005	99
Raza, S	PI-P-001	180	Rossi, JP	PB-P-004	203
Recillas, M	APS-P-007	97	Rossing, C	CPS-P-028	106
Reggi, VR	ABS PS1-1	17	Rouse, MJA	ABS G04-1	52
Reggi, VR	BIO PS1-1	16	Rouse, MJA	BIO G04-2	50
Reis, AMM	PP-P-001	205	Routledge, P	AS-O-006	95
Reis, AMM	PP-P-002	205	Rozmanic, VR	HPS-P-051	146
Reis, AMM	PP-P-003	205	Rudolf, M	HPS-P-005	135
Reis, JR	MEPS-P-004	179	Ruggli, M	CPS-P-054	113
Reis, MC	PP-P-002	205	Rupret, S	CPS-P-081	120
Reis, SO	IPS-P-037	169	Rupret, S	CPS-P-094	123
Rekman, E	CPS-P-076	118	Ryszka, F	BB-P-012	193
Renaudeau, C	MEPS-P-001	179	Saeki, Y	ABS G24	89
Renu Singh, D	IPS-P-020	164	Sahlin Olofsson, B	CPS-P-052	112
Repolés, LC	CPS-P-003	100	Sai, Y	PI-P-002	180
Rey, A	ABS S6-12	38	Sajjadi Tabassi, SA	NS-P-007	197
Rey, A	BIO S6-9	34	Sakai, MC	HPS-P-004	134
Rhee, D	CPS-P-018	104	Sakai, MC	HPS-P-006	135
Rhee, J-D	IPS-P-007	161	Sakai, MC	HPS-P-027	140
Rhee, J-D	IPS-P-008	161	Sakai, MC	HPS-P-030	141
Rhee, J-D	IPS-P-009	162	Sakakibara, M	CPS-P-119	129
Rhee, J-D	IPS-P-010	162	Saksripanit, P	CPS-P-111	127
Ribeiro Gurgel, JA	PI-P-018	184	Sales, F	HPS-P-065	150
Ribeiro, E	HPS-P-004	134	Salkicevic, B	HPS-P-010	136
Ribeiro, E	HPS-P-027	140	Salkicevic, SB	PP-P-006	206
Ricachenevsky, C	PI-P-029	187	Samu, AS	CPS-P-012	102
Ricci, MC	HPS-P-027	140	Sangpuk, J	CPS-P-111	127
Riis, K	CPS-P-085	121	Sankarankutty, AK	APS-P-008	97
Riise, MR	CPS-P-045	111	Sankarankutty, AK	CPS-P-100	124
Rios, RCC	APS-P-007	97	Santana, G	CPS-P-101	125
Roberson, CR	HPS-P-011	136	Santana, G	HPS-P-087	155
Roberson, CR	HPS-P-013	137	Santana, GS	HPS-P-094	157
Roberts, G	AS-O-006	95	Santos Jr, G	CPS-P-088	121
Robles, AM	NR-P-003	201	Santos, ACD	CBS-P-002	98
Rocha, CR	IPS-P-036	168	Santos, J	HPS-P-065	150
Rocha, HVA	IPS-P-031	167	Santos, J	LMCS-P-008	177
Rocha, HVA	IPS-P-039	169	Santos, K	IPS-P-049	172
Rodrigues, CP	HPS-P-027	140	Santos, K	IPS-P-050	172
Rodrigues, D	HPS-P-072	151	Santos, LL	APS-P-008	97
Rodrigues, JM	CPS-P-088	121	Santos, LL	CPS-P-100	124
Rodrigues, MC	CPS-P-021	105	Santos, MO	HPS-P-007	135
Rodrigues, MC	PP-P-015	208	Santos, T	CPS-P-107	126
Rodrigues, ML	CPS-P-088	121	Saraf, S	PB-P-002	203
Rolim Neto, PJ	IPS-P-036	168	Saraf, S	PB-P-002	203
Rolim Neto, PJ	IPS-P-037	169	Saraiva, T	AS-O-008	95
Rolim Neto, PJ	IPS-P-038	169	Saraiva, T	CPS-P-109	127
Rolim, C	QP-P-011	212	Sarkar, S	IPS-P-015	163
Rolim, CMB	IPS-P-034	168	Sasaki, H	HPS-P-028	140
Rolim, CMB	IPS-P-038	169	Saseen, J	ABS P1-1	7
Rolim, CMB	QP-P-011	212	Saseen, J	BIO P1-1	6
Rolim, CMB	QP-P-012	212	Sato, S	BB-P-005	192
Roque Martins, A	HPS-P-089	156	Sauer, D	IPS-P-013	163
Roque Piñero, E	QP-P-001	210	Savage, I	AS-O-003	94

Author Index

Author	Code	page	Author	Code	page
Savage, I	PI-O-002	188	Sial, S	PI-O-009	190
Savic, S	LMCS-P-007	177	Siau, A	ABS G24	89
Savio Quevedo, E	ABS G02-7	49	Siegel, JS	HPS-P-086	155
Savio, E	ABS S6-07	36	Silva Diógenes Nogueira, JH	MEPS-P-004	179
Savio, E	ABS S6-13	38	Silva Júnior, DB	APS-P-008	97
Savio, E	BIO G02-6	47	Silva Júnior, DB	CPS-P-100	124
Savio, E	BIO S6-1	32	Silva, A	IPS-P-043	170
Savio, E	CPS-P-110	127	Silva, A	IPS-P-044	170
Savio, E	CPS-P-110	127	Silva, A	IPS-P-045	171
Savio, E	NR-P-003	201	Silva, A	IPS-P-046	171
Savio, E	NR-P-003	201	Silva, A	IPS-P-048	171
Savio, E	NR-P-006	202	Silva, A	IPS-P-049	172
Savio, E	NR-P-006	202	Silva, A	IPS-P-050	172
Schaefer, M	BIO G11-0	63	Silva, AEBC	HPS-P-098	158
Schall, VT	CPS-P-058	114	Silva, AEBC	HPS-P-098	158
Schapoval, E	QP-P-013	213	Silva, AEBC	HPS-P-099	158
Schenkel, EP	NS-P-014	199	Silva, AEBC	HPS-P-099	158
Schenkel, EP	NS-P-015	199	Silva, AEBC	HPS-P-101	159
Schenkel, EP	NS-P-016	199	Silva, CMD	CBS-P-005	99
Schenkel, EP	NS-P-017	200	Silva, E	CPS-P-051	112
Schmidt, FS	BIO P3-0	11	Silva, E	CPS-P-068	116
Schmølker, LSC	CPS-P-045	111	Silva, E	IPS-P-049	172
Schneider, MP	CPS-P-083	120	Silva, E	IPS-P-050	172
Schneider, MP	CPS-P-091	122	Silva, E	PI-P-011	182
Schulz, M	ABS G02-2	48	Silva, E	PP-P-018	209
Schulz, M	ABS P2-3	9	Silva, G	IPS-P-045	171
Schulz, M	BIO G02-2	46	Silva, G	IPS-P-046	171
Schulz, M	BIO P2-2	8	Silva, G	IPS-P-047	171
Schulz, M	CPS-P-059	114	Silva, G	IPS-P-048	171
Schumacher, G	AS-P-004	91	Silva, I	AS-O-008	95
Seghal, P	HPS-P-063	149	Silva, I	CPS-P-109	127
Seimerson, M	CPS-P-079	119	Silva, IS	ABS G04-2	52
Serafimovska, S	HPS-P-083	154	Silva, IS	BIO G04-3	51
Seyoum, D	ABS G22-1	87	Silva, JMFS	IPS-P-002	160
Seyoum, D	BIO G22-0	86	Silva, LAM	PP-P-019	209
Shaakhemodova, ShZ	LMCS-P-010	178	Silva, LAM	PP-P-020	209
Shah, AN	CBS-P-001	98	Silva, M	CPS-P-101	125
Shah, AN	HPS-P-003	134	Silva, RMF	IPS-P-038	169
Shah, DK	IPS-P-022	165	Silva, S	IPS-O-004	173
Shah, R	AS-O-003	94	Sinanovic, N	HPS-P-010	136
Shamsuddin, AF	BB-P-006	192	Sinanovic, SN	PP-P-006	206
Shanmugam, S	CPS-P-018	104	Sipetic, SS	CPS-P-093	123
Shaw, J	AS-P-007	92	Sipetic, T	CPS-P-093	123
Shaw, SM	ABS S6-02	35	Sippel, J	QP-P-013	213
Shaw, SM	ABS S6-09	37	Sitthiworanan, C	PI-P-014	183
Shaw, SM	BIO S6-3	32	Skarin, P	CPS-P-065	116
Sheikh, A	PI-O-009	190	Skrbic, RS	APS-P-001	96
Sheikh, A	PI-P-001	180	Smith, H	ABS G13-4	67
Sheikh, AL	HPS-P-046	145	Smith, H	BIO G13	66
Shen, AY	CPS-P-077	119	Soares, M	PI-P-021	185
Shen, X	HPS-P-103	159	Soares, RRS	IM-P-001	215
Shetty, M	CPS-P-015	103	Söderberg, J	CPS-P-057	114
Shetty, M	NS-P-003	196	Soeiro, O	CPS-P-099	124
Shibuya, FS	HPS-P-080	153	Soeiro, O	PI-P-023	185
Shih, HC	LMCS-P-006	177	Soeiro, O	PP-P-013	208
Shih, RL	LMCS-P-006	177	Solarovic, T	CPS-P-044	110
Shiohira, H	BB-P-001	191	Solarovic, T	PI-P-024	185
Shiram, SS	HPS-P-014	137	Solarovic, T	PI-P-025	186

Author Index

Author	Code	page	Author	Code	page
Solich, P	LMCS-P-009	178	Surugue,	HPS-P-061	149
Solich, P	LMCS-P-009	178	Surugue, JS	ABS G17-2	74
Solichová, D	LMCS-P-009	178	Surugue, JS	BIO G17-3	73
Sonar, VV	CBS-P-001	98	Suszka-Switek, A	BB-P-012	193
Sonar, VV	HPS-P-003	134	Suturkova, S	HPS-P-083	154
Søndergaard, M	AS-O-005	95	Suzuki, T	CPS-P-119	129
Sonnekus, J	IPS-P-012	162	Suzuki, Y	HPS-P-042	144
Sørensen, G	CPS-P-053	113	Suzuki, YS	HPS-P-039	143
Sorensen, L	CPS-P-028	106	Svensson, CM	CPS-P-063	115
Šostar, Z	PP-P-007	206	Svensson, E	CPS-P-078	119
Šostar, Z	PP-P-008	206	Swaan, W	BIO S1	21
Sousa, AB	CBS-P-002	98	Swanepoel, E	BB-P-014	194
Sousa, AB	HPS-P-004	134	Syed, S	HPS-P-046	145
Sousa, AB	HPS-P-006	135	Syed, SR	HPS-P-046	145
Sousa, AB	HPS-P-027	140	Tai, HS	HPS-P-064	149
Souza, GS	HPS-P-093	157	Tai, SH	HPS-P-021	139
Souza, K	IPS-P-041	170	Takagi, CA	HPS-P-027	140
Souza, LM	HPS-P-093	157	Takahashi, H	HPS-P-082	154
Souza, VR	IM-P-001	215	Takahashi, PSK	HPS-P-004	134
Spinosa, HS	CBS-P-002	98	Takahashi, PSK	HPS-P-027	140
Splavski Kandic, B	CPS-P-060	114	Takeda, MES	IPS-O-006	174
Srividya, P	NS-P-003	196	Takeishi, K	BB-P-005	192
Stefanovic, D	PI-P-007	181	Tamayo, L	ABS S4-4	29
Stenseke, IM	CPS-P-033	108	Tamayo, L	BIO S4-4	28
Steppe, M	QP-P-008	211	Tang, CS	CPS-P-077	119
Steppe, M	QP-P-013	213	Taqueda, ME	BB-P-004	191
Sterjev, Z	HPS-P-083	154	Tarn, Y	HPS-P-104	159
Stevenson, JG	HPS-P-009	136	Tasic, Lj	CPS-P-047	111
Stig Haugbølle, L	AS-O-005	95	Tasic, Lj	CPS-P-067	116
Stig Haugbølle, L	CPS-P-034	108	Tasic, Lj	CPS-P-067	116
Stig Haugbølle, LSH	AS-O-007	95	Tavares pereira, M	APS-P-003	96
Štimac, D	PP-P-007	206	Tavares, N	PP-P-016	208
Štimac, D	PP-P-008	206	Tavares, N	PP-P-017	209
Štimac, D	PP-P-008	206	Tayo, F	CPS-P-117	129
Štimac, D	PP-P-009	207	Tchebotarenco, S	PI-O-003	188
Štimac, Š	PP-P-009	207	Teixeira, T	HPS-P-054	147
Stoisavljevic Satara, SSS	APS-P-001	96	Tellingner, K	BIO G20-0	79
Stojanovic, S	CPS-P-048	111	Terán Gretter, MA	ABS S6-11	37
Stojanovic, S	CPS-P-067	116	Terán Gretter, MA	BIO S6-8	34
Storpirtis, SS	ABS S2-2	25	Teräsalmi, EK	ABS G02-6	49
Storpirtis, SS	BIO S2-2	23	Thengungal, R	QP-P-006	211
Stupar, D	CPS-P-047	111	Thielke, S	ABS P2-2	9
Stupar, D	HP-O	133	Thomas, D	CPS-P-002	100
Stupar, D	HP-P-002	130	Thomsen, A	CPS-P-027	106
Stupar, D	HP-P-003	130	Thorsell, E	CPS-P-098	124
Stupar, M	CPS-P-047	111	Tileekeva, U	PI-O-003	188
Stupar, M	CPS-P-106	126	Tillaeva, G	LMCS-P-002	176
Stupar, M	HP-O	133	Tillaeva, G	LMCS-P-003	176
Stupar, M	HP-P-002	130	Tillaeva, G	LMCS-P-010	178
Su, L	HPS-P-084	154	Tillaeva, UM	LMCS-P-003	176
Su, Y-H	CPS-P-041	110	Tiwari, P	PI-O-004	188
Sugawara, ER	HPS-P-027	140	Tokuyama, E	IPS-P-006	161
Sui, S	QP-P-005	211	Tomasiunas, G	CPS-P-110	127
Sukthong, D	CPS-P-111	127	Tomic, S	PP-P-007	206
Sun, MF	PI-P-013	183	Tomic, S	PP-P-008	206
Sundström-Nilsson, B	CPS-P-038	109	Tomsen, DT	AS-O-007	95
Sung, SL	HPS-P-079	153	Tomsen, DV	CPS-P-028	106
Suppamong, W	CPS-P-112	127	Toskic Radojicic, M	LMCS-P-004	176

Author Index

Author	Code	page	Author	Code	page
Toskic Radojicic, M	LMCS-P-005	177	Vega, EM	CPS-P-103	125
Toskic Radojicic, M	PI-P-004	180	Vega, EM	CPS-P-103	125
Toskic Radojicic, M	PP-P-004	205	Vega, EM	HPS-P-095	157
Toskic-Radojicic, M	HPS-P-015	137	Vega, EM	HPS-P-095	157
Toskic-Radojicic, M	HPS-P-025	140	Vegfors, E	CPS-P-052	112
Tousset, E	CPS-P-091	122	Velasco, MVR	BB-P-004	191
Travieso Novelles, MC	QP-P-001	210	Velasco, MVR	IPS-O-006	174
Travieso Novelles, MC	QP-P-002	210	Venkateswarlu, V	IPS-P-011	162
Trbakovic, A	HPS-P-010	136	Verissimo, L	IPS-P-040	169
Trbakovic, TA	PP-P-006	206	Verissimo, L	IPS-P-041	170
Trigo, TD	PI-P-023	185	Verissimo, L	IPS-P-042	170
Trigo, TD	PP-P-013	208	Verissimo, L	IPS-P-043	170
Trisic, V	CPS-P-048	111	Verissimo, L	IPS-P-044	170
Tromp, ThFJ	ABS G02-5	49	Verissimo, L	IPS-P-045	171
Tromp, ThFJ	ABS R2-5	5	Verissimo, L	IPS-P-046	171
Tromp, ThFJ	BIO G02-5	47	Verissimo, L	IPS-P-047	171
Tromp, ThFJ	BIO R2-5	3	Verissimo, L	IPS-P-048	171
Tsai, C-Y	APS-P-005	97	Verissimo, L	IPS-P-049	172
Tsai, C-Y	APS-P-006	97	Verissimo, L	IPS-P-050	172
Tsai, C-Y	HPS-P-073	152	Vermeulen, LC	BIO R2-8	3
Tsai, JC	HPS-P-021	139	Vestergaard, E	CPS-P-124	130
Tsai, JT	CPS-P-041	110	Viçosa, AL	IPS-P-039	169
Tsai, PC	HPS-P-043	144	Vidotti, C	CPS-P-068	116
Tsai, T	HPS-P-041	144	Vidotti, C	PI-P-011	182
Tsai, YR	CPS-P-074	118	Vidotti, C	PP-P-018	209
Tsai, YR	CPS-P-075	118	Vidotti, CCF	ABS G05-1	55
Tsai, YW	PI-P-008	181	Vidotti, CCF	ABS G15-2	70
Tseng, Y-M	HPS-P-073	152	Vidotti, CCF	ABS G22-2	87
Tseng, YT	HPS-P-059	148	Vidotti, CCF	BIO G05-1	53
Tsuchiya, F	HPS-P-020	138	Vidotti, CCF	BIO G15-2	68
Tsuchiya, F	HPS-P-029	141	Vidotti, CCF	BIO G22-1	86
Tsuji, E	IPS-P-006	161	Vidotti, CCF	BIO R1-0	1
Tsukiji, MT	PI-P-002	180	Vieira, L	NS-P-013	199
Tufts-Conrad, D	PI-O-008	189	Vieira, LMM	NS-P-013	199
Tully, M	CPS-P-098	124	Vieira, MT	HPS-P-072	151
Turcic, P	HPS-P-005	135	Vieira, N	CPS-P-104	125
Uchida, T	IPS-P-006	161	Vieira, N	CPS-P-105	126
Uema, SAN	CPS-P-016	103	Vigil, SV	CBS-P-007	99
Uema, SAN	CPS-P-103	125	Vigil, SV	CBS-P-008	99
Uema, SAN	HPS-P-095	157	Villafuerte-Robles, R	IPS-P-001	160
Ueta, JU	APS-P-008	97	Villafuerte-Robles, R	IPS-P-004	160
Ueta, JU	CPS-P-100	124	Villares, RS	HPS-P-095	157
Ugwuanyi, IO	IPS-P-003	160	Villoch Cambas, A	QP-P-001	210
Urbanc Mokotar, M	CPS-P-094	123	Villoch Cambas, A	QP-P-002	210
Vaillancourt, R	ABS G24	89	Virovkic-Zunec, B	HPS-P-037	143
Valadares Freitas, I	CPS-P-004	100	Vlasic Cicvaric, IVC	HPS-P-049	146
Valadares Freitas, I	CPS-P-005	101	Vlasic Cicvaric, IVC	HPS-P-050	146
Valadares Freitas, IVF	CPS-P-050	112	Vrijens, B	CPS-P-091	122
Vamshi, M	CPS-P-015	103	Vrushali Walknis, V	IPS-P-023	165
Van de Vaart, FJ	BIO PS2-0	18	Vrzic-Petronijevic, S	HPS-P-002	134
Van Mil, JWF	ABS R2-5	5	Vukelja, J	CPS-P-106	126
Van Tonder, EC	BB-P-014	194	Vukušic, I	PP-P-007	206
Van Vollenhoven, R	HPS-P-023	139	Vukušic, I	PP-P-008	206
Van Wyk, CJ	IPS-P-012	162	Vukušic, I	PP-P-009	207
Vanegas Escamilla, EP	ABS S6-05	36	Wable, PJ	CBS-P-001	98
Vanegas Escamilla, EP	BIO S6-5	33	Wable, PJ	HPS-P-003	134
Vega, EM	CPS-P-016	103	Wang, CYW	HPS-P-016	137
Vega, EM	CPS-P-016	103	Wang, G	HPS-P-026	140

Author Index

Author	Code	page	Author	Code	page
Wang, J	BB-P-003	191	Yanaguimoto, HY	BB-P-002	191
Wang, J	CPS-P-030	107	Yang, CL	PI-P-008	181
Wang, JC	CPS-P-074	118	Yang, C-W	IPS-O-007	174
Wang, WF	CPS-P-074	118	Yang, C-W	IPS-P-007	161
Wang, Z	QP-P-007	211	Yang, C-W	IPS-P-025	166
Waning, J	ABS G06	58	Yang, J	LMCS-P-011	178
Waning, J	ABS G10-2	62	Yang, RC	NS-P-005	197
Waning, J	BIO G06	57	Yang, RC	PI-P-013	183
Waning, J	BIO G10-2	61	Yang, T	CPS-P-073	118
Wardell, SMS	IPS-P-039	169	Yang, Y	HPS-P-103	159
Watanabe, MW	CPS-P-023	105	Yang, YK	HPS-P-038	143
Watanabe, Y	BB-P-001	191	Yang, YK	HPS-P-045	145
Weatherman, KD	ABS S6-04	36	Yen, SC	HPS-P-070	151
Weatherman, KD	ABS S6-06	36	Yen, Y-H	HPS-P-058	148
Weatherman, KD	BIO S6-6	33	Yen, Y-H	HPS-P-067	150
Weich, A	QP-P-011	212	Yetsko, Y	PI-O-003	188
Weich, A	QP-P-012	212	Yong, CS	IPS-O-007	174
Weich, A	QP-P-012	212	Yong, CS	IPS-P-007	161
Weich, AW	BB-P-015	194	Yong, CS	IPS-P-008	161
Weir, K	CPS-P-066	116	Yong, CS	IPS-P-009	162
Wendel, AM	CPS-P-011	102	Yong, CS	IPS-P-010	162
Wertheimer, I	ABS G21-2	84	Yong, CS	IPS-P-024	165
Wertheimer, I	BIO G11-0	63	Yong, CS	IPS-P-025	166
Wertheimer, I	BIO G21-2	82	Yong, CS	IPS-P-026	166
Westerlund, T	CPS-P-022	105	Yong, CS	IPS-P-027	166
Westerlund, T	CPS-P-032	107	Yong, CS	IPS-P-028	166
Westh Sorensen, E	AS-O-007	95	Yoo, B	CPS-P-018	104
Westh Sorensen, E	PI-P-010	182	Yoo, B	CPS-P-018	104
Westh Sørensen, E	CPS-P-095	123	Yoo, B-K	IPS-O-007	174
White-Means, S	PI-O-005	189	Yoo, B-K	IPS-P-007	161
Williams III, RO	ABS S1	22	Yoo, B-K	IPS-P-008	161
Williams III, RO	BIO S1	21	Yoo, B-K	IPS-P-009	162
Williams III, RO	IPS-P-013	163	Yoo, B-K	IPS-P-010	162
Williams, RLW	ABS S1	22	Yoo, B-K	IPS-P-024	165
Williams, RLW	ABS S5	31	Yoo, B-K	IPS-P-025	166
Williams, RLW	BIO S1	21	Yoo, B-K	IPS-P-026	166
Williams, RLW	BIO S5	30	Yoo, B-K	IPS-P-027	166
Womeodu, R	PI-O-005	189	Yoo, B-K	IPS-P-028	166
Wood, EJ	PB-P-006	204	Yoshino, N	HPS-P-042	144
Wu, C	LMCS-P-011	178	Yoshino, NY	HPS-P-039	143
Wu, CC	HPS-P-043	144	Yu, CT	HPS-P-021	139
Wu, H	BB-P-003	191	Yu, KY	CPS-P-041	110
Wu, JB	CBS-P-003	98	Yusuf, E	BB-P-006	192
Wu, M-S	HPS-P-067	150	Zabé, D	MEPS-P-001	179
Wu, Y	QP-P-005	211	Zafalon, PJ	CPS-P-123	130
Wuliji, T	ABS G15-6	71	Zaha, A	CBS-P-005	99
Wuliji, T	BIO G15-1	68	Zaheer, F	HPS-P-046	145
Xavier, F	IPS-P-045	171	Zaki, AM	IPS-P-005	161
Xavier, F	IPS-P-046	171	Zecevic, M	LMCS-P-007	177
Xavier, F	IPS-P-047	171	Zecevic, ZM	LMCS-P-001	176
Xavier, F	IPS-P-048	171	Zenda, H	HPS-P-020	138
Ximenes, SCC	NS-P-012	198	Zhang, W	IM-P-002	215
Xuan, J-J	IPS-P-009	162	Zigic, ZG	LMCS-P-001	176
Xuan, J-J	IPS-P-024	165	Zivanovic, Lj	LMCS-P-001	176
Xuan, J-J	IPS-P-025	166	Zivanovic, Lj	LMCS-P-007	177
Xuan, J-J	IPS-P-028	166	Zolcsak, RQ	HPS-P-004	134
Yamaguchi, AM	HPS-P-027	140	Zolezzi, M	AS-P-007	92
Yamamura, S	HPS-P-056	147	Zolezzi, M	AS-P-007	92

Author Index

Author	Code	page
Zolezzi, M	HPS-P-063	149
Zolezzi, M	HPS-P-063	149
Zumbach, S	CPS-P-084	120
Zumec, IZ	HPS-P-037	143