



Innovation with Quality and Experience

Introduction

With the recent breakthrough of generic drugs in the market, companies have become clearly aware of the need to provide high quality services in the pharmaceutical industry.

Relying on a team of specialized professionals familiarized with the whole process of solving problems in drug research, this is Synchrophar's purpose.

Synchrophar has an ongoing concern about continuous improvement in developing and managing clinical projects, in order to meet its clients needs. Our actions are driven by promptness, safety and practicability.

Synchrophar is proud to rely on highly qualified professionals who are constantly tuned with the market.



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This training is delivered to all collaborators: physicians, nurses, assistant nurses, laboratory technicians, pharmacists, biochemists, and biologists.

All of this is to ensure reliability, promptness in achieving results and providing top quality services. We are in tune with our clients' quality standards and needs.

Synchrophar has gathered business coherence with the academic experience of its researchers to provide high quality services, at competitive prices, and dedicate special attention to voluntary subjects in clinical trials.



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About the Company

Founded in 2000, in the city of Campinas, State of São Paulo, Brazil, *Synchrophar Assessoria e Desenvolvimento de Projetos Clínicos* was the first private company in the Bioequivalence Research field.

Over the years, Synchrophar has evolved in clinical research projects to meet not only the needs of its clients, but also those of the community, employees, sponsors, government, and other parties interested in its organizational performance.

Synchrophar's clinical and statistical phases are currently accredited by the Brazilian Health Authority ("ANVISA") and our analytical unit is under primary certification.



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Mission, Vision and Values



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Mission

To promote continuous improvement of quality of life through bioequivalence research of renowned therapeutic value drugs for human health, providing benefits for industries, volunteers, and collaborators.



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Vision

To be a leading and innovative company in clinical projects, always committed to provide the best services to industries, volunteers and collaborators.



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Values

- Ethics;
- Commitment;
- Innovation and
- Transparency



Responsibility and Quality

Synchrophar's responsibilities are based on guidelines imposed by national and international agencies always focusing on service excellence and the safety of collaborators and volunteers.

Within this scenario, the quality of our services becomes a consequence that can be easily visualized by the company's solidity and figures.



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Responsibility and Quality

More than 600 studies carried out.

Providing services for over 55 national and international companies.

More than 80 direct and indirect collaborators with broad experience and knowledge in Clinical Research.

Partnership with large and medium-sized hospitals and clinical analysis laboratories.

Maintains a database with more than 12,000 volunteers.



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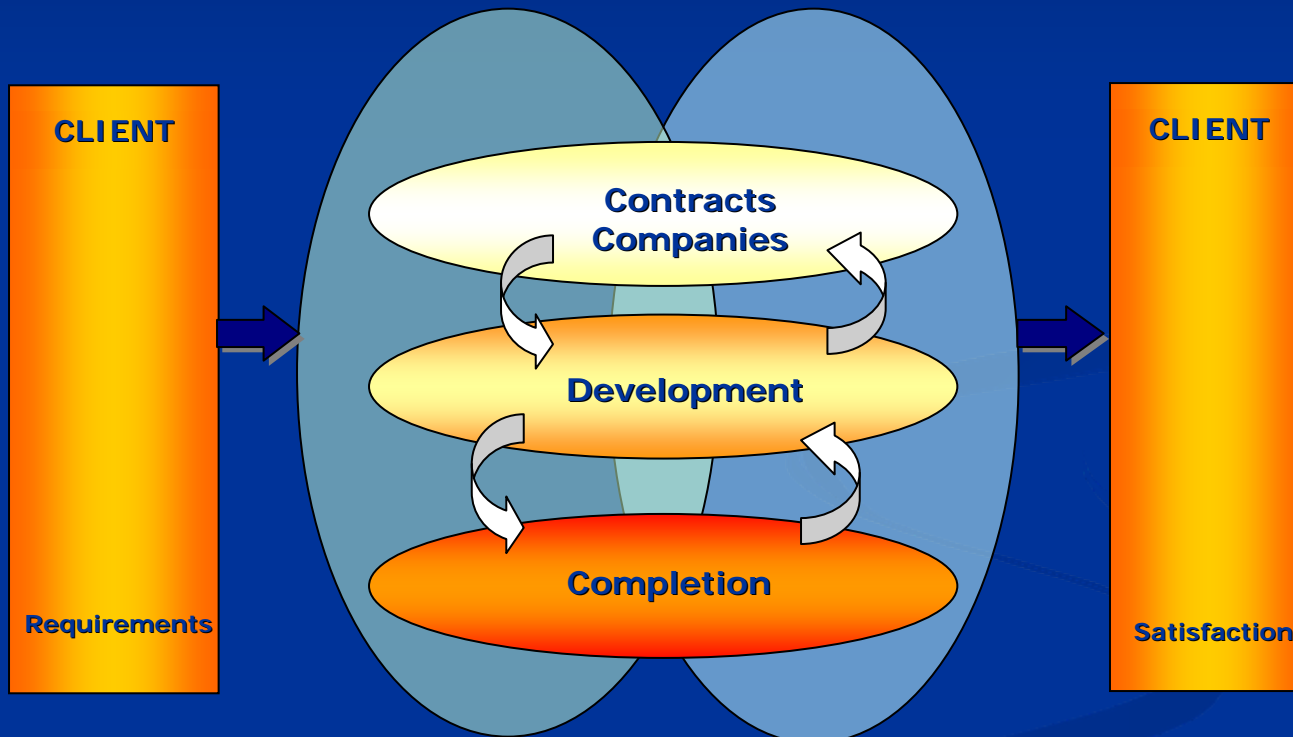
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Quality Management System

Synchrophar endeavors to maintain a high quality standard for all its processes. Therefore, the company has established an organizational structure based on three large activity groups in order to commission its management system for a continuous improvement of its efficacy.



Sequence and Interaction of Major Processes



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Quality Assurance System

Synchrophar also establishes and keeps duly documented procedures to control documents regarding the Quality Assurance System requirements, including, to the extent applicable, external documents, such as those from companies/sponsors.



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Quality Assurance System Framework

Level	Documents	Type
Strategic	Quality manual	Normative
	Guidelines	
	Quality Policy	
Tactic	SOPs	Normative
	Flowcharts	
	External standards	
Operational	Instructions	Strategic
	Lists	
	External Documents	
	Quality Records	

The Quality Assurance Unit establishes monitoring and internal audit schedules, so as the processes are always controlled and gradually improved.



Clinical trial Service

Synchrophar is specialized in carrying out bioequivalence/ bioavailability studies designed for the pharmaceutical industry. Thanks to its experience, Synchrophar can assure the clinical development of protocols, procedures required for selecting volunteers, drug administration, and sample collection for analysis according to GCP requirements.



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Facilities



Facilities

Currently, Synchronphar performs its activities in the following units:

- Clinical Unit (Cândido Gomide st.)
- Confinement Units (Irmãos Penteado Hospital - Campinas-, São Francisco Hospital – Americana-, Bairral Foundation – Itapira-, Penido Burnier Institute – Campinas-)
- Archive Unit (César Bierrenbach st.)
- Administrative Unit (César Bierrenbach st.)

Staff

- Approximately 80 professionals of multiple areas are linked to Synchrophar:

Medical Doctors of a wide array of specialties, nurses, biologists, geneticists, pharmacists, statisticians, psychologists, laboratory technicians, informatics professionals, etc.

Alliances and agreements

In order to provide the broadest scope of services and activities, Synchrophar promotes politics of alliances and agreements with several companies, hospitals and professionals.

Volunteers



Approximately 12,000 volunteers recorded in its database have access to laboratory examinations according to the protocol approved. Before confinement, each volunteer is examined by the physician to check for inclusion/exclusion criteria.



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Volunteers



The professionals collect: clinical history, including medical history, physical examination (including 12-lead ECG, BP, temperature, and heart rate), laboratory clinical examinations, including Hematological Analysis, Biochemical Analysis, Urine I and BHCG for women (pre and post-study examinations), and serology in pre-study examination only. All documentation pertinent to GCP.



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Clinical Unit – Hospital Irmãos Penteados

Hospitalization Units

Unit located in the 2nd floor of the hospital, with an installed capacity of 39 beds, distributed in 2-bed rooms without bathroom, and 5-bed rooms with bathroom. The Unit has a nursing center equipped with emergency trolley and a specific room for centrifugation with 02 freezer, 02 refrigerated centrifuge, AC, and a computer sample processing system which includes bar coding follow up.

The hospital has an Intensive Care Unit with 11 beds on the same floor.

Volunteers hospitalized in this unit are transported by a bus company specialized in passenger transportation, accompanied by an assistant nurse

To meet ANVISA's regulatory requirements for site certification, the hospital has a Health Permit and Hospital Infection Control Commission.

Ambulatory Unit

The site has an ambulatory unit where the volunteer selection process, off-site collections, and volunteers follow-up until the completion of the clinical study are carried out.



Phase I, II, III, and IV Clinical Studies

Our experience has been gained by carrying out phase I to IV Clinical Pharmacology Studies, including publications in journals and international congresses.

All studies are developed and carried out strictly according to national and international standards, such as GCP/ICH, Helsinki Declaration, Nuremberg Code, National Resolution No. 196/1996 (Ministry of Health), FDA and EMEA regulations.



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Bioequivalence

The scientific base according to which reference drugs are compared to their generic equivalents. The studies should be conducted to ensure that the two products are not different as to safety, efficacy, and bioavailability when administered at the same dosages.



Such studies are conducted under ANVISA protocols (Brazilian Health Authority - www.anvisa.gov.br) protocols.



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Bioequivalence

Two drugs are bioequivalent if they are equivalent or pharmaceutical alternatives, and if the bioavailability rates and extension (after administration at the same molar dose) are similar in such degree that their effects with respect to efficacy and safety are essentially the same.



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Certification - ANVISA

Synchrophar`s Research Site is duly certified by the Brazilian Regulatory Agency, as disclosed:
(<http://www.anvisa.gov.br/medicamentos/bioequivalencia/centros/nacionais/certificados.asp#sp15>).

SYNCHROPHAR - Assessoria e Desenvolvimento de Projetos Clínicos S/C Ltda
CERTIFICAÇÃO: Resolução RE nº 323 de 05 de fevereiro de 2009

HISTÓRICO
RESPONSÁVEIS

COORDENADOR DO CENTRO: Claudia Cristiana Domingues
GERENTE DA GARANTIA DA QUALIDADE: Sandro Evandir Oliveira
RESPONSÁVEL PELA ETAPA CLÍNICA: Dr. Ronilson Agnaldo Moreno
RESPONSÁVEL PELA ETAPA ESTATÍSTICA: Rogério Antônio de Oliveira

SEDE DO CENTRO DE BIOEQUIVALÊNCIA
Endereço: Rua César Bierreinbach, 24, Conjuntos 51 e 52, Campinas – São Paulo – CEP: 13015-025
Tel/Fax: (19) 3234-2834 / (19) 3234-0572
E-mail: coordenacao@synchrophar.com

ETAPA CLÍNICA
Nº total de leitos: 115

UNIDADE CLÍNICA DE INTERNAÇÃO: Seleção e recrutamento
Endereço: Rua Engenheiro Cândido Gomide nº 595 - Jardim Guanabara - Campinas-SP CEP: 13073-200
Tel/Fax: 19 3233-7300 / 19 3233-6383
E-mail: coordenacao@synchrophar.com

UNIDADE CLÍNICA DE INTERNAÇÃO: Irmandade de Misericórdia de Campinas – Hospital Irmãos Penteados
Endereço: Av. Benjamin Constant, 1657, Centro – Campinas – SP – CEP: 13010-142
Tel/Fax: 19 3737-7000
E-mail: adminhosp_imc@terra.com.br

UNIDADE CLÍNICA DE INTERNAÇÃO: Irmandade de Misericórdia de Americana – Hospital São Francisco
Endereço: Praça Francisco Matarazzo, 60, Vila Galo – Americana – SP – CEP: 13466-319
Tel/Fax: 19 3475-9901
E-mail: eduardo@hsfamericana.com.br

UNIDADE CLÍNICA DE INTERNAÇÃO: Fundação Espírita "América Bairral"
Endereço: Rua Dr. Hortêncio Pereira da Silva, 313, Centro - Itapira – SP – CEP: 13970-905
Tel/Fax: (19) 3863-9400
E-mail: bairral@bairral.com.br

UNIDADE CLÍNICA DE INTERNAÇÃO: Instituto Penido Burnier/ ICC Hospital e Pronto Socorro do Coração Ltda
Endereço: Rua Dr. Mascarenhas, 249, Botafogo – Campinas – SP – CEP: 13970-905
Tel/Fax: (19) 3232-5866
E-mail: penido@penidoburnier.com.br

LABORATÓRIO DE ANÁLISES CLÍNICAS: Laboratório de Análises Clínicas Lab-Clin S/C Ltda

Concluído, mas contém erros na página.

Certification – ANVISA

Synchrophar`s Research Site is duly certified by the Brazilian Regulatory Agency, as disclosed:
(<http://www.anvisa.gov.br/medicamentos/bioequivalencia/centros/nacionais/certificados.asp#sp15>).

The screenshot shows a Windows Internet Explorer browser window with the address bar containing the URL: <http://www.anvisa.gov.br/medicamentos/bioequivalencia/centros/nacionais/certificados.asp#sp15>. The page content is a list of certified centers and laboratories, organized into several sections:

- UNIDADE CLÍNICA DE INTERNAÇÃO: Irmandade de Misericórdia de Americana – Hospital São Francisco**
Endereço: Praça Francisco Matarazzo, 60, Vila Galo – Americana – SP – CEP: 13466-319
Tel/Fax: 19 3475-9901
E-mail: eduardo@hsfamericana.com.br
- UNIDADE CLÍNICA DE INTERNAÇÃO: Fundação Espírita "América Bairral"**
Endereço: Rua Dr. Hortêncio Pereira da Silva, 313, Centro - Itapira – SP - CEP: 13970-905
Tel/Fax: (19) 3863-9400
E-mail: bairral@bairral.com.br
- UNIDADE CLÍNICA DE INTERNAÇÃO: Instituto Penido Burnier/ ICC Hospital e Pronto Socorro do Coração Ltda**
Endereço: Rua Dr. Mascarenhas, 249, Botafogo – Campinas – SP – CEP: 13970-905
Tel/Fax: (19) 3232-5886
E-mail: penido@penidoburnier.com.br
- LABORATÓRIO DE ANÁLISES CLÍNICAS: Laboratório de Análises Clínicas Lab-Clin S/C Ltda**
Responsável técnico: Sebastião Gonçalves Borges
Endereço: Rua Domingos Nardini, 54 – Vila Medon – Americana – SP - CEP: 13.465-120
Tel/Fax: 19 3461-2446
E-mail: labclin@labclin.etc.br
- LABORATÓRIO DE ANÁLISES CLÍNICAS: Centralab Diagnóstico Clínico S/C Ltda**
Responsável técnico: Ronaldo Selmi
Endereço: Rua José Milani, 467 – Jardim Vila Rosa – Valinhos – SP – CEP:13.270-260
Tel/Fax: 19 3869-3099
E-mail: marcia@centralanalises.com.br
- LABORATÓRIO DE ANÁLISES CLÍNICAS: Labclínicas Laboratório de Análises Clínicas Sonchini e Melo Ltda Fil 001**
Responsável técnico: Luis Roberto Melo
Endereço: Rua Marechal Deodoro, 235 – Centro – Campinas – SP – CEP:13.010-300
Tel/Fax: 19 3233-0570/ 3739-4032
E-mail: alexandre@labclinicas.com.br

ETAPA ESTATÍSTICA
Endereço: Rua César Bierreinbach, 24, Conjuntos S1 e S2, Campinas – São Paulo – CEP: 13015-025
Tel/Fax: (19) 3234-2834 / (19) 3234-0572
E-mail: foerico@synchrophar.com

T&E Analítica Comércio e Análises Químicas Ltda.

At the bottom of the browser window, a status bar indicates: "Concluído, mas contém erros na página." and the zoom level is set to 100%.

Certificate of Good Practices in Bioavailability/ Bioequivalence in Drugs



MINISTÉRIO DA SAÚDE
Agência Nacional de Vigilância Sanitária
Gerência Geral de Medicamentos

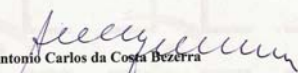
CERTIFICADO DE BOAS PRÁTICAS EM BIODISPONIBILIDADE/BIOEQUIVALÊNCIA DE MEDICAMENTOS

Número/Ano: 05/2007

Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, Decreto n.º 3.029 de 16 de abril de 1999, e a Resolução-RE n.º 102 de 12 de janeiro de 2007, publicada no Diário Oficial da União em 15 de janeiro de 2007, certifico que o centro a seguir descrito cumpre com a legislação sanitária vigente, de acordo com as normas exigidas pela Autoridade Sanitária Brasileira, estando suas instalações sujeitas a inspeções periódicas.

RAZÃO SOCIAL: SYNCHROPHAR- Assessoria e Desenvolvimento de Projetos Clínicos S/C Ltda.		
CNPJ: 03.765.587/0001-18		
ENDEREÇO: Rua Engenheiro Cândido Gomide nº 38		CEP: 13073-200
BAIRRO: Botafogo	MUNICÍPIO: Campinas	UF: SP
Certificado de Boas Práticas em Biodisponibilidade/Bioequivalência de Medicamentos:		
Certificamos que o Centro acima mencionado realiza a(s) seguinte(s) etapa(s) do estudo de Biodisponibilidade/Bioequivalência de Medicamentos:		
Etapa Clínica		
Etapa Estatística.		

Válido até: 15/01/2008.
Brasília, DF, 10/05/2007.


Antonio Carlos da Costa Bezerra
Gerente Geral de Medicamentos

Este Certificado só terá valor quando levar o selo seco do Órgão de Vigilância Sanitária do MS



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Material resources

All material collected is properly processed and stored, according to the strictest quality standards. Besides having the most state-of-the-art and sophisticated equipment and methods available to perform its work, such as mass spectrometers and immunoassays used for exact quantification of drugs.

Such material is collected during the clinical research and stored in freezer at -80°C .



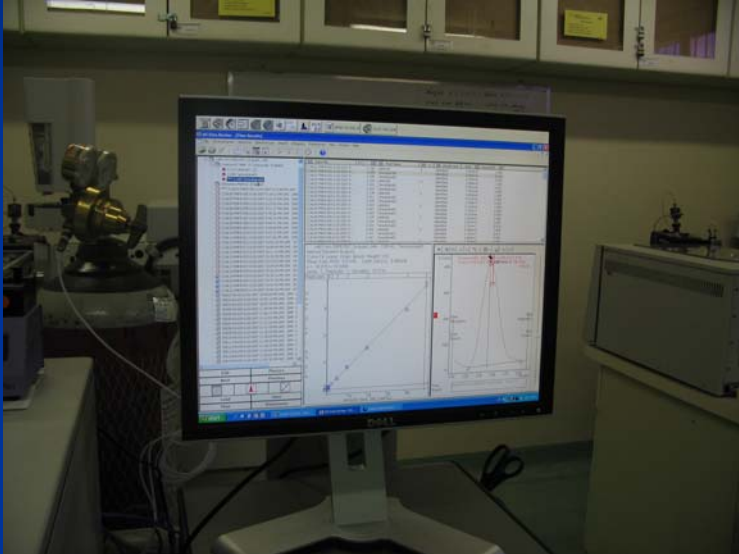
Such material is collected during the clinical research and stored in freezer at -80°C .



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Data generation



Data generated by researches are managed through software, where it synchronizes technology and capacity of storage of results and following up of each process of clinical research.

The software has capacity for controlling the study of a certain drugs and as differential the capacity of going beyond a simple issuing of cards.



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List of Researched Drugs

ACECLOFENAC	CIPROFLOXACIN	LEVOTHYROXINE
ACECLOFENAC + CYCLOBENZAPRINE	CYPROTERONE + ETHYNILESTRADIOL	LISINOPRIL
ACICLOVIR	CITALOPRAM	LORATADINE
ACETYLSALICYLIC ACID (feeding)	CLARITHROMYCIN	LORATADINE + BETAMETHASONE
ACETYLSALICYLIC ACID (fasting)	CLINDAMYCIN	LOSARTAN + HYDROCHLORIDE
MEFENAMIC ACID	CLONAZEPAM	LOSARTAN
TRANEXAMIC ACID	CLOZAPINE	LOVASTATIN
AMILORIDE + HYDROCLOROTIAZIDA	DEFLAZACORT	ENALAPRIL MALEATE
AMINOPHILINE	DESOGESTREL	MELOXICAM
AMIODARONE	DIAZEPAM	MEMANTINE
AMITRIPTYLINE	CHOLESTYRAMINE DICLOFENAC	METFORMIN
AMOXICILLIN	DICLOFENAC POTASSIUM	METFORMIN (feeding)
AMOXICILLIN (capsule)	DICLOFENACO SODIUM	METOPROLOL
AMOXICILLIN (suspension)	DIDANOSINE	METHOTREXATE
AMPICILLIN (capsule)	DIGOXIN	METRONIDAZOLE
AMPICILLIN (suspension)	SODIUM DIVALPROATE (feeding)	MIDAZOLAM
ANASTROZOLE	SODIUM DIVALPROATE (fasting)	MODAFENIL
AMLODIPINE	DOMPERIDONE	NIMESULIDE (tablets)
AMLODIPINE + LOSARTAN + CHLORTALIDONE	DOXAZOSIN	NIMESULIDE (suspension)
ATENOLOL	ENALAPRIL	NIMODIPINE
ATORVASTATIN	SPIRONOLACTONE	NORFLOXACIN
AZITHROMYCIN (tablets)	ETHYNILESTRADIOL + DESOGESTREL	OMEPRAZOLE
AZITHROMYCIN (suspension)	PHENYTOIN	PANTOPRAZOLE
AMLODIPINE BESYLATE	PHENOXYMETHYLPENICILLIN	PAROXETINE
BETAMETHASONE	FEXOFENADINE	PENTOXYPHYLLINE (feeding)



List of Researched Drugs

BETAMETHASONE + DEXCHLORPHENIRAMINE	FINASTERIDE	PENTOXYPHYLLINE (fasting)
BICALUTAMIDE	FLUCONAZOLE	PIROXICAM
BROMAZEPAM	FLUNARIZINE	PREDNISOLONE
BROMOPRIDE	FLUOXETINE	PROPRATYLNITRATE
BROMPHENIRAMINE + PSEUDOEPHEDRINE	FLUTAMIDE	PROPRANOLOL
BUFLOMEDIL	FUROSEMIDE	RAMIPRIL
BUPROPION (feeding)	GABAPENTIN	RIBAVIRIN
BUPROPION (fasting)	GEMFIBROZIL	RIFAMPICINA + ISONIAZID
CAPTOPRIL	GESTODENE + ETHYNIESTRADIOL	RISPERIDONE
CARBAMAZEPINE	GLIBENCLAMIDE	RITONAVIR
LITHIUM CARBONATE	GLIMEPIRIDE	RIVASTIGMINE
CARVEDILOL	IBANDRONATE	SALBUTAMOL
CEFADROXIL (capsules)	IBUPROFEN	SECNIDAZOLE
CEFADROXIL (suspension)	INDINAVIR	SELEGILINE
CEPHALEXINE (tablets)	ISOSORBIDE	SERTRALINE
CEPHALEXINE (suspension)	ISOTRETINOIN	SULFAMETHOXAZOLE + TRIMETHOPRIM
KETOCONAZOLE	ITRACONAZOLE (feeding)	SUMATRIPTAN
KETOPROFEN	ITRACONAZOLE (fasting)	TAMOXIPHEN
CYCLOBENZAPRINE	LAMIVUDINE + ZIDOVUDINE + NEVIRAPINE	TAMSULOSIN (Feeding)
CILOSTAZOL	LAMOTRIGINE	TAMSULOSIN (Fasting)
CIMETIDINE	LETROZOLE	TICLOPIDINE
CINNARIZINE	LEVOFLOXACIN	TINIDAZOLE
CIPROFLOXACIN	LEVONORGESTREL + ETHYNIESTRADIOL	TRAMADOL + KETOPROFEN
CYPROTERONE + ETHYNIESTRADIOL	VENLAFAXINE	TRIAMCINOLONE
WARFARIN SODIUM	VERAPAMIL	ZIDOVUDINE