EMENTA

Dados Básicos

Programa:	DESENVOLVIMENTO E INOVAÇÃO TECNOLÓGICA EM MEDICAMENTOS (23001011047P1)
Nome:	ESTUDO DE ESTABILIDADE DE MEDICAMENTOS
Sigla:	DIT
Número:	0010
Créditos:	1
Período de Vigência:	01/01/2012 à -
Disciplina obrigatória:	Não
Ementa:	A disciplina visa relacionar temas avançados aplicados ao estudo de estabilidade de medicamentos. Abordando aspectos relacionados com as interações e incompatibilidades em fármacos-excipientes, reações de degradações, cinética e modelos matemáticos aplicados ao estudo de estabilidade de produtos farmacêuticos. Além de avaliar a aplicação deste estudo na regulamentação, registro e comercialização dos medicamentos.
Bibliografia:	BALTEZOR, M. Physico-chemical criteria for the stability and stability forecast of solid dosage forms. In. GRIMM, W.; THOMAE, K. eds. Stability testing of pharmaceutical products. Sttutgart: Wissenschaftliche Verlagsgesellschaft, 1987. 238p. Bhalekar M, Madgulkar A, Patel B, et al. Complexes: Role in pharmaceutical formulation. ASIAN JOURNAL OF CHEMISTRY. V.19, Issue: 4. p 26152622. 2007. CARSTENSEN, J.T. Drug stability: principles and practices. v.43. New York: Marcel Dekker, 1990. CASADIO, S. Tecnologia farmacêutica. 2.ed. Milano: Cisalpino- Goliardica, 1972. Chow, S. and Liu, J. (1995). Statistical Design and Analysis in Pharmaceutical Science: Validation, Process Controls, and Stability. New York: Marcel Dekker, Inc. CONNORS, K.A.; AMIDON, G.L.; STELLA, V.L. Chemical stability of pharmaceuticals: a handbook for pharmacists. New York: John Wiley, 1986. 847p. CPMP, 2003. CPMP/QWP/122/02, rev 1, 2003. Guideline on stability testing: stability testing of existing active substances and related finished products. Committee for proprietary medicinal products, London, UK. CPMP, 2003. CPMP/QWP/609/96/Rev 1, 2003. Note for guidance on declaration of storage conditions: A: in the product information of medicinal products, B: for active substances. Committee for proprietary medicinal products, London, UK. D.L. Hertzog, J.F. McCafferty, X. Fang, R.J. Tyrell and R.A. Reed, Development and validation of a stability-indicating HPLC method for the simultaneous determination of losartan potassium, hydrochlorothiazide, and their degradation products, J. Pharm. Biomed. Anal. 30 (2002), pp. 747?760. DAGAR, V.D. Factors affecting the stability of pharmaceutical products. East. Pharm., New Delhi, n.6, p.41-42, 1990. FDA Guidance for Industry (Draft), 1998. Drug Stability Testing of Drug Substances and Drug Products. ICH Q1A(R2), 2003. Stability testing guidelines: stability testing of new drug substances and products. ICH Steering Committee. ICH. Stability Testing Of New Drug Substances And Products Q1A (R2), 2003. Disponivel em http://www.ich.org/MediaServer.jser?@_ID=419&@_MODE=GLB. INTERNATIONAL CONFERENCE ON HARMONIZATION. Stability testing of new drug substances and products. Disponivel em: http://www.ich.org. K.E. McCarthy, Q. Wang, E.W. Tsai, R.E. Gilbert, D.P. Ip and M.A. Brooks, Determination of losartan and its degradates in Cozaar® tablets by reversed-phase high-performance thin-layer chromatography, J. Pharm. Biomed. Anal. 17 (1998), pp. 671?677. Khawam A, Flanagan DR. Basics