Nº. 90

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Y BIBLIOTECA

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BIBLIOGRAFIA

Tema: Impurezas en productos

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No.	Registros	Solicitud
1	3319	impurities
2	7980	drugs
* 3	128	impurities and drugs

Registro 1 de 9 - Analytical Abstracts
TI: Active drug substance impurity profiling part I. LC-UV diode-array spectral matching.
AU: Nicolas,-EC; Scholz,-TH
AD: DuPont Merck Pharm. Co., Deepwater, NJ 08023, USA
CP: USA
SO: J-Pharm-Biomed-Anal. Jan 1998; 16(5): 813-824
JN: Journal-of-Pharmaceutical-and-Biomedical-Analysis
IS: 0731-7085
CO: JPBADA
PY: 1998
LA: English
PT: Journal
AB: UV diode-array spectral matching was used online after HPLC to characterize impurity profiles of drugs. DuP 941 a potential anti-cancer drug was used as a model analyte. A UV spectral library was generated for several impurities of DuP 941 from the earliest safety lot. Impurities in subsequent lots were then investigated and their spectral characteristics were compared with those contained in the spectral library. The technique was found to be very sensitive being capable of detecting impurity levels of ~0. 1%. The method was found to be strongly influenced by the detector sensitivity lamp intensity and the presence of other impurities with similar UV spectra.
IA: drugs-A: detection of impurities in, by LC-UV diode-array spectral matching
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 6008G00016
UD: 6008

Registro 2 de 9 - Analytical Abstracts
TI: Drug impurity profiling strategies.
AU: Gorog,-S; Babjak,-M; Balogh,-G; Brlik,-J; Csehi,-A; Dravecz,-F; Gazdag,-M; Horvath,-P; Lauko,-A; Varga,-K
AD: Chem. Works Gedeon Richter Ltd., 1475 Budapest, Hungary
CP: Hungary
SO: Talanta. Sep 1997; 44(9): 1517-1526
JN: Talanta
IS: 0039-9140
CO: TLNTA2
PY: 1997
LA: English
PT: Journal
CF: Presented at Euroanalysis IX, held in Bologna, Italy, Sep 1996
AB: A scheme for the determination of impurities in bulk drugs is described, which involves chromatographic, spectrometric and hyphenated techniques. The scheme is illustrated using the analysis of a variety of drugs as examples. It involves initial analysis by TLC, HPLC or GC using standards for identification of impurities. If identification is not possible further analysis by UV spectrophotometry (e.g. using a diode-array detector in HPLC) or densitometry (e.g. in TLC) followed by preparative TLC or HPLC and MS, GC-MS or HPLC-MS analysis. If identification is still not achieved NMR or HPLC-NMR analysis is necessary. The suggested impurities are then synthesized enabling their identity to be confirmed by retention matching. Identification of impurities in propanidid and allylesterol by GC-MS and HPLC and identification of impurities in mazipredone by HPLC-MS and HPLC are described in some detail.
IM: drugs-M: identn. of impurities in, by chromatography and spectrometry, schemes for
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 6001G00009
UD: 6001

Registro 3 de 9 - Analytical Abstracts
TI: Simultaneous resolution and detection of a drug substance, impurities, and counter ion using a mixed-mode HPLC column with evaporative light scattering detection.
AU: Lantz,-MD; Risley,-DS; Peterson,-JA
AD: Lilly Corp. Center, Pharm. Sci. Div., Indianapolis, IN 46285, USA
CP: USA
SO: J-Liq-Chromatogr-Relat-Technol. May 1997; 20(9): 1409-1422
JN: Journal-of-Liquid-Chromatography-and-Related-Technologies
IS: 1082-6076
CO: JLCTFC
PY: 1997
LA: English
PT: Journal
AB: LY 326315 was used as a model drug. Samples were prepared in aqueous 50% methanol. Analysis was performed by HPLC on a 7 micro m mixed-mode phenyl/cation column (25 cm x 4.6 mm i.d.) with methanol/0.1M-ammonium acetate buffer of pH 4.5 (1:1) as mobile phase (

1 ml/min) and evaporative light scattering detection (28degreeC, 1 bar and a gain of 7). The method allowed the simultaneous detection of a drug substance, impurities and counter ions in a single chromatogram (some example chromatograms are illustrated). Results are discussed.
IA: drugs-A: detection of, and their counter-ions and impurities, by HPLC
IC: chromatography,-liquid,-high-performance-C: in pharmaceutical analysis
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 5908G00017
UD: 5908

Registro 4 de 9 - Analytical Abstracts
TI: Determination of drug-related impurities by capillary electrophoresis.
AU: Altria,-KD
AD: Glaxo Wellcome Res. and Dev., Anal. Sci., Ware, Herts. SG12 0DP, UK
CP: UK
SO: J-Chromatogr,-A. 31 May 1996; 735(1-2): 43-56
JN: Journal-of-Chromatography,-A
IS: 0021-9673
CO: JCRAEY
PY: 1996
LA: English
PT: Journal
AB: A review with 58 references is presented dealing with the progress of capillary electrophoresis in determining impurities in drugs. Reports are sub-divided into low-pH, high-pH and MEKC applications. Potential developments are also covered, these including the use of electrolyte additives, developments in instrumentation and the increased use of electrochromatography.
IM: pharmaceutical-preparations-M: detmn. of drug-related impurities in, by capillary electrophoresis, review
IC: electrophoresis,-capillary-C: in detmn. of drug-related impurities, review
SC: G-Pharmaceutical-Analysis
SS: 00100
CR: B4
COP: Copyright: The Royal Society of Chemistry
AN: 5811G00011
UD: 5811

Registro 5 de 9 - Analytical Abstracts
TI: Impurities in drug substances and drug products: new approaches to quantification and qualification.
AU: Berridge,-JC
AD: Pfizer Central Res., Anal. Res. Dev., Kent CT13 9NJ, UK
CP: UK
SO: J-Pharm-Biomed-Anal. Dec 1995; 14(1-2): 7-12
JN: Journal-of-Pharmaceutical-and-Biomedical-Analysis
IS: 0731-7085
CO: JPBADA
PY: 1995
LA: English
PT: Journal
CF: Presented at the Sixth International Symposium on Pharmaceutical and Biomedical Analysis, held in St. Louis, MO, USA, 23-26 Apr, 1995
AB: The implications of recent guidelines set by the International Conference on Harmonization for the identification, qualification and control of impurities in drugs and their formulated products are discussed. Consideration is given to both their regulatory impact and the impact on analytical technology. Methods for the qualification of impurities which do not involve additional studies are suggested.
IM: drugs-M: analysis of, for impurities, guidelines for;
pharmaceutical-preparations-M: analysis of, for impurities, guidelines for
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 5808G00018
UD: 5808

Registro 6 de 9 - Analytical Abstracts
TI: Estimation of impurity profiles in drugs and related materials. XI. Role of chromatographic and spectroscopic methods in the estimation of side-reactions in drug syntheses.
AU: Gorog,-S; Balogh,-G; Csehi,-A; Csizer,-E; Gazdag,-M; Halmos,-Z; Hegedus,-B; Herenyi,-B; Horvath,-P; Lauko,-A
AD: Chem. Works G. Richter Ltd., 1475 Budapest, Hungary
CP: Hungary
SO: J-Pharm-Biomed-Anal. 1993; 11(11-12): 1219-1226
IS: 0731-7085
CO: JPBADA
PY: 1993
LA: English
PT: Journal
CF: Presented at the Fourth International Symposium on Pharmaceutical and Biomedical Analysis held in Baltimore, MD, USA, April 18-21, 1993
AB: A review, with 23 references, is presented indicating the source of impurities in drugs, viz, those that originate from unreacted intermediates during synthesis, impurities from reactions with solvents, impurites from catalysts, and those from side-reations, over-reaction, and further reactions of the formed drugs with the reagents or solvents.

All of these are explored with knowledge of the synthesis process and the standard analytical procedures of all forms of chromatography and spectrometry. (cf. Anal. Abstr., 1993, 55, 11E111).
IM: drugs-M: analysis of, review;
pharmaceutical-preparations-M: analysis of, review
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 5606G00019
UD: 5606

Registro 7 de 9 - Analytical Abstracts
TI: Novel approach in the structure determination of an impurity in the presence of a pharmaceutical compound.
AU: Cholli,-AL; White-Rafalko,-P; Ezell,-EF; Kosarych,-Z; Ellgren,-AJ
AD: BOC Group, Tech. Center, Murray Hill, NJ 07974, USA
CP: USA
SO: Appl-Spectrosc. Feb 1990; 44(2): 175-183
IS: 0003-7028
CO: APSPA4
PY: 1990
LA: English
PT: Journal
AB: The proposed method involves slow crystallization to enrich the impurity concn. in relation to the pharmaceutical compound. The NMR spectrum of the impurity-enriched phase (in soln. or crystallite form) is compared with that of the original sample; this allows determination of impurity structure and concn. The technique is illustrated by the identification of an impurity in an enamide derivative; the impurity enrichment was achieved in a co-crystalline form. One- and two-dimensional NMR were used, and the structure of the impurity was confirmed by X-ray diffraction and high-resolution MS. The technique demonstrates the feasibility of identifying impurities without prior isolation.
IM: pharmaceutical-preparations-M: detmn. of impurities in, by crystallization - NMR;
drugs-M: detmn. of impurities in, by crystallization - NMR
SC: G-Pharmaceutical-Analysis
SS: 00100
COP: Copyright: The Royal Society of Chemistry
AN: 5302G00001
UD: 5302

Registro 8 de 9 - Analytical Abstracts
TI: Purity determination and evaluation of new drug substances.
AU: Van-Rompay,-J
AD: Janssen Pharmaceutica, 2340 Beerse, Belgium
CP: Belgium
SO: J-Pharm-Biomed-Anal. 1986; 4(6): 725-732
IS: 0731-7085
CO: JPBADA
PY: 1986
LA: English
PT: Journal
CI: A.E.J.
AB: A review is presented, including determination of impurities, and their origins and allowable limits. (12 references).
IM: drugs-M: detmn. of impurities in, review
IC: pharmaceutical-analysis-C: detmn. of purity in, review
SC: E-Pharmaceutical-chemistry
SS: 00000
COP: Copyright: The Royal Society of Chemistry
AN: 4907E00001
UD: 4907

Registro 9 de 9 - Analytical Abstracts
TI: Characterization of drug purity by liquid chromatography.
AU: Jansson,-S-O
AD: AB Hassle, Anal. Chem., 431 83 Molndal, Sweden
CP: Sweden
SO: J-Pharm-Biomed-Anal. 1986; 4(5): 615-624
IS: 0731-7085
CO: JPBADA
PY: 1986
LA: English
PT: Journal
CI: G.C.
AB: A review is presented, with 30 references, of separation of impurities in drugs.
IM: drugs-M: sepn. of impurities in, by LC, review
SC: E-Pharmaceutical-chemistry
SS: 00000
COP: Copyright: The Royal Society of Chemistry
AN: 4905E00003
UD: 4905