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(54) **A direct solid sample analytical technology for determining a content and a uniformity thereof in a lyophilized kit of a sulfur-containing chelator with a stable complex capacity for radiotechnetium (Tc-99m) and radiorhenium (Re-186, Re-188)**

(57) The present invention is related to a direct solid sample analytical technology for determining a content and a uniformity thereof in a lyophilized kit of a sulfur-containing chelator with a stable complex capacity for radiotechnetium (Tc-99m) and radiorhenium (Re-186, Re-188),wherein an elemental analyzer coupled with a non-dispersive infrared detector, a thermal conductivity detector or an isotope ratio mass spectrometer is applied to a direct analysis of a solid lyophilized sample. Further, an economical, stable and easily accessible coal standard is used herein as a contrast substance to construct a sulfur calibration curve, followed by obtaining the sulfur content and the uniformity thereof in the solid lyophilized sample by interpolating the foregoing result into the sulfur calibration curve. Then, the weight content percent is converted to get the content and the uniformity of the chelator in the lyophilized kit. The quality control of active pharmaceutical ingredients (API) in the lyophilized kit during key production processes and clinical applications is thus assured.

FIG.1A

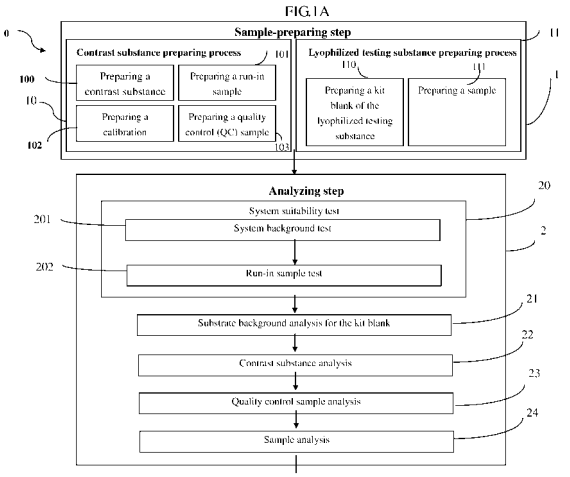

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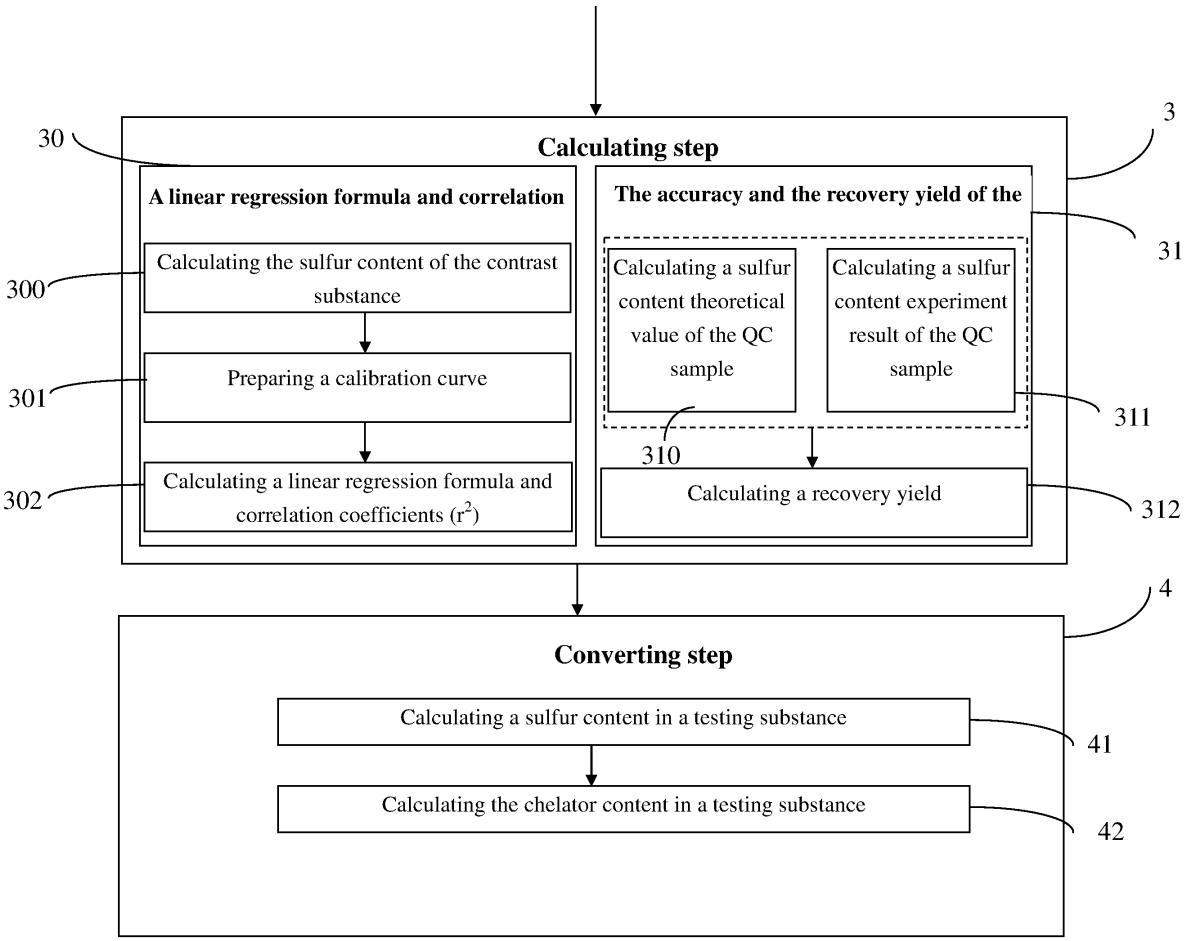
FIG. 1B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Calculating step
A linear regression formula and correlation
The accuracy and the recovery yield of the
31
Calculating the sulfur content of the contrast substance
300
Calculating a sulfur content theoretical value of the QC sample
Calculating a sulfur content experiment result of the QC sample
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Preparing a calibration curve
301
310
Calculating a linear regression formula and correlation coefficients (r^2)
302
Calculating a recovery yield
312
4
Converting step
Calculating a sulfur content in a testing substance
41
Calculating the chelator content in a testing substance
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EUROPEAN SEARCH REPORT

Application Number
EP 11 40 1610

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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A	SIEPER H-P ET AL: "A measuring system for the fast simultaneous isotope ratio and elemental analysis of carbon, hydrogen, nitrogen and sulfur in food commodities and other biological material", RAPID COMMUNICATIONS IN MASS SPECTROMETRY, vol. 20, no. 17, 1 January 2006 (2006-01-01), pages 2521-2527, XP55020966, ISSN: 0951-4198, DOI: 10.1002/rcm.2619 * the whole document *	1-3	TECHNICAL FIELDS SEARCHED (IPC) G01N A61K
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	23 March 2012	Johnson, Keith

CATEGORY OF CITED DOCUMENTS

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X,P	MING-YU CHAO ET AL: "Direct determination of ECD in ECD kit: a solid sample quantitation method for active pharmaceutical ingredient in drug product", JOURNAL OF BIOMEDICINE AND BIOTECHNOLOGY, vol. 2011, 1 January 2011 (2011-01-01), pages 1-7, XP55020842, ISSN: 1110-7243, DOI: 10.1155/2011/196238 * the whole document * -----	1-8	

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23-03-2012

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