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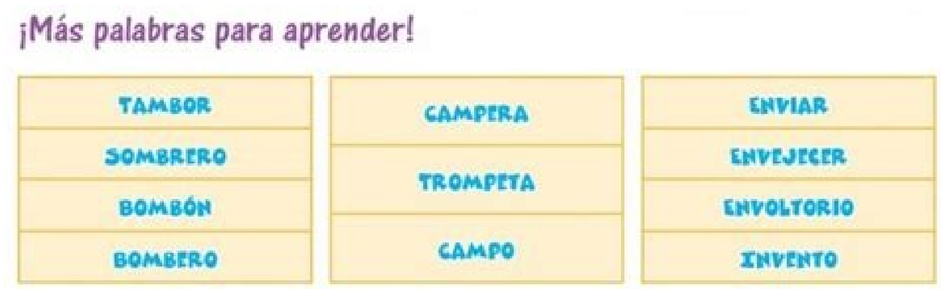
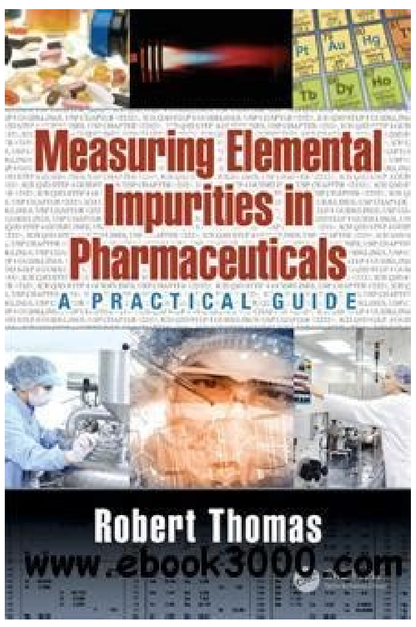
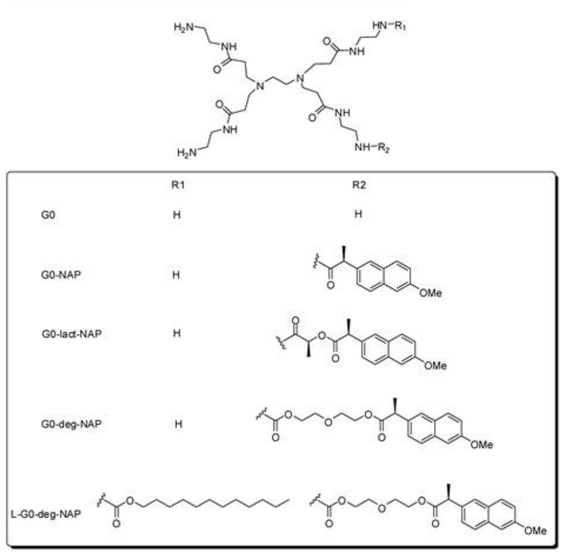


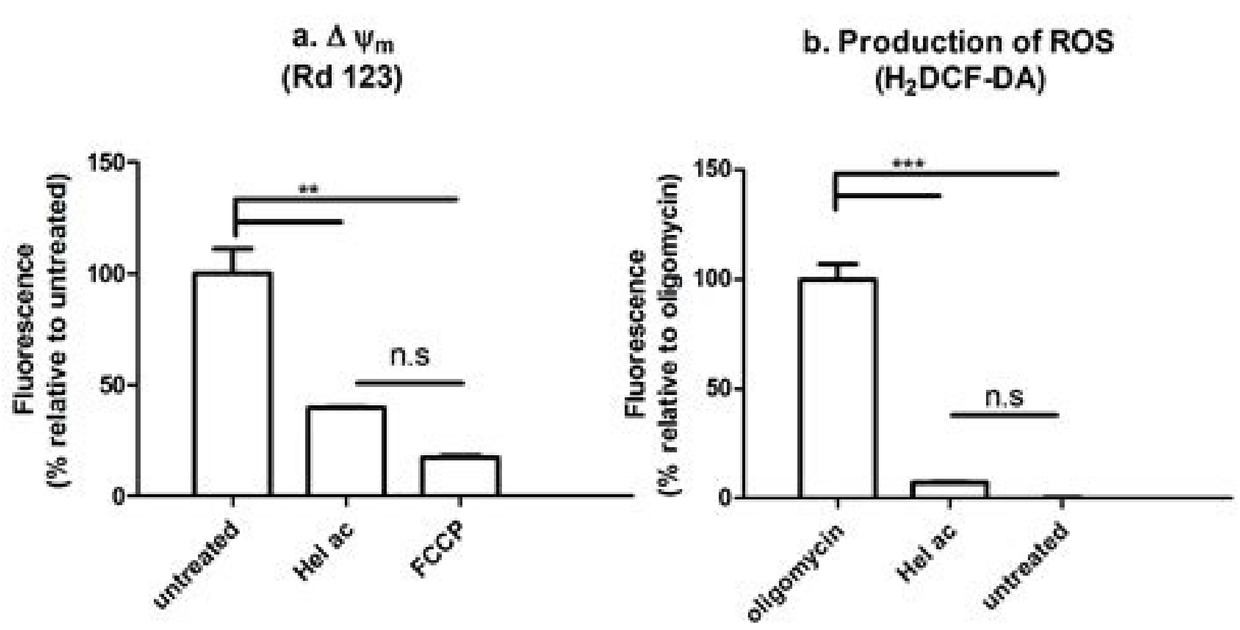




Session I-Pa 3d

Monitoring Human Rights in Latin America with the Assistance of Statistical Information

Nancy CARDIA



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This means that the Related substances test can detect and control the impurities listed in the drug substance monograph for Aspirin (Ph. Eur. It is important to note the word 'about'. More information on the status and interpretation of the labelling section can be found in Supplementary Chapter I G Labelling. Guidance on the control of impurities and on calculating limits can be found in SC I A. Use a detection wavelength of 237 nm. If the monograph title is listed here, apply a limit of not less than 70% of the label claim in 45 minutes. Where a word/phrase is in italics, it means it is connected to another section of the BP. MOBILE PHASE 2 volumes of orthophosphoric acid, 400 volumes of acetonitrile and 600 volumes of water. The (3%) figure indicates the limit as a percentage relative to the amount of Aspirin in the test solution and is given for information. Secondary peaks exclude the drug substance(s), reagents, internal standards and derivatising agents. However, it is more common for the limiting solution to be a dilution of the test solution. CHROMATOGRAPHIC CONDITIONS Use a stainless steel column (25 cm × 4.6 mm) packed with octadecylsilyl silica gel for chromatography (5 µm) (Kromasil C18 is suitable). If the monograph is not listed in SC I E, follow the decision tree in section 3.3 of the same supplementary chapter. The General Notices: provide useful information on using the BPexplain that a product should comply with the monograph, if testedexplain which sections of the monographs are mandatory & which are advisoryexplain that alternative tests to the ones described in the monograph can be used. The tablets must comply with the Tablets general monograph. The label states that the tablets contain Aspirin, unless this word appears in the name of the tablets. SYSTEM SUITABILITY The test is not valid unless, in the chromatogram obtained with solution (3) the resolution between the peaks due to aspirin and impurity C is at least 6.0. DETERMINATION OF CONTENT Calculate the content of C9H8O4 in the tablets from the chromatograms obtained using the declared content of C9H8O4 in aspirin BPCRS. Measure the absorbance of a suitable solution of aspirin BPCRS using dissolution medium in the reference cell. monograph 0309, Acetylsalicylic Acid). Aspirin Tablets contain Aspirin. This is not exhaustive and is usually aligned with the entry in the British Approved Names (BAN) publication. The declared content of a BPCRS can be found in the online catalogue and in the leaflet. The tablets comply with the requirements stated under Tablets and with the following requirements. If a numerical limit is given, the figure will be shown in the limits section without parenthesis e.g. 'the total impurities are not greater than 2.0%'. Aspirin is the British Approved Name (BAN) i.e. the non-proprietary name for acetylsalicylic acid in the UK (see Appendix XXI B Approved Synonyms for further details). Use an ambient column temperature. PROCEDURE After 45 minutes withdraw a sample of the medium and measure the absorbance of the filtered sample, suitably diluted with the dissolution medium if necessary, at the maximum at 265 nm, Appendix II B using dissolution medium in the reference cell. Allow the chromatography to proceed for 1.2 times the retention time of impurity F. The methods in the monograph are the official methods which support the standard. The official title of the product in the UK. In this case the Aspirin monograph (Ph. Eur. If the limit is written as 'the sum of the areas of any other secondary peaks' then the sum should not include any impurities that have specific limits applied to them. A dilution of the test solution (solution (1)) is another common way of preparing a limiting solution. Q value limits were not applied to monographs published before BP 2008; the requirements of Appendix XII B. Appendix III Chromatographic Separation Techniques includes details on making adjustments to chromatographic conditions. CHROMATOGRAPHIC CONDITIONS The chromatographic procedure described under Related substances may be used. DETERMINATION OF CONTENT Calculate the total content of aspirin, C9H8O4, in the medium using the declared content of C9H8O4 in aspirin BPCRS. BP monographs are designed for products that are manufactured within the quality framework for medicinal products. If the system suitability requirement (below) is met, and the impurities can be detected/identified, the retention time does not need to be exactly 5 minutes. When applied within this framework, the identification test (or tests) in the monograph are sufficient to confirm that the drug product contains the drug substance on the label. In this case, the reagent entry for absolute ethanol in Appendix I A. Monographs of the British Pharmacopoeia apply in these cases, and the monographs affected are listed in SC I E Dissolution Testing of Solid Oral Dosage Forms. This name should not be used when marketing products in the UK. The tests contained in this section of the monograph are to determine quality attributes of the product. Use a flow rate of 1.0 mL per minute. Ambient temperature should be taken to mean between 15 to 25 °C. Check the More Resources section in the online BP for example test results (if there are some available). Peaks that are due to the mobile phase, sample matrix, excipients and counter-ions can also be disregarded. However, alternative methods can be used if the user can demonstrate that it gives an equivalent measure of the requirement. More details on secondary peaks can be found in Appendix III Chromatographic Separation Techniques – Quantification and Appendix III D Liquid Chromatography – Additional points for monographs of the British Pharmacopoeia. Labelling requirements in monographs are not comprehensive and the requirements of the regulatory authority where the product is marketed should be met. In this example, if there is a peak corresponding to impurity C in the sample, it should not be included within the sum of any 'other secondary peaks'. This requirement does not apply in countries where exclusive proprietary rights in the name Aspirin are claimed. The content is written in terms of the label claim of the product, which may not match the full title of the drug substance monograph. This test is designed to provide limits for potential impurities related to the drug substance, rather than all possible impurities such as adulterants or contaminants. The brand/manufacturer of the column that was used when the monograph method was established is provided for information. Where there is no 'Limits' section following 'Determination of content' in the monograph, check section 3.4 of Supplementary Chapter I E Dissolution Testing of Solid Oral Dosage Forms. Monographs first published in BP 2008 or afterwards should comply with Appendix XII B. This is

stated in the General Notices Part II, in the section on 'Assays and Tests'. Disregard any peak with an area less than 0.25 times the area of the principal peak in the chromatogram obtained with solution (2) (0.05%). The drug substance used to manufacture the tablets must comply with the relevant Ph Eur or BP monograph for that substance. The General Notices require that, unless stated otherwise, assays and tests are performed between 15 to 25 °C. Pharmacopoeial Calculations. Content of aspirin, C9H8O4 95.0 to 105.0% of the stated amount Shake a quantity of the powdered tablets containing 0.5 g of Aspirin with 20 mL of absolute ethanol, filter (Whatman GF/C is suitable), evaporate the filtrate and dry the residue at 60° for 1 hour. 20 units is traditionally accepted as a statistical representation of a batch. Inject 20 µL of each solution. Use isocratic elution and the mobile phase described below. Advisory information on the most common indication(s). The impurities limited by the requirements of this monograph include those listed under Aspirin. The product must comply with the requirements of the tests. Appendix III Chromatographic Separation Techniques gives details of how to measure resolution. In this example, the limit of the impurity is determined against an external standard of the impurity. When the chromatograms are recorded under the prescribed conditions, the retention times relative to aspirin (retention time about 5 minutes) are: impurity A, about 0.6; impurity B, about 0.7, impurity C, about 1.4 and impurity F, about 8.0. SYSTEM SUITABILITY The test is not valid unless, in the chromatogram obtained with solution (4) the resolution between the peaks due to aspirin and impurity C is at least 6. This is common when the drug substance used to manufacture the product is in a salt form. Control of Impurities and SC VI A. The tablets must contain 95.0 to 105.0% of the amount stated on the label for the shelf life of the product. There is likely to be variation due to the use of different equipment and columns. The reagent used should comply with the criteria stated in the appendix entry. It is not a numerical limit. TEST CONDITIONS Use Apparatus 1, rotating the basket at 50 revolutions per minute. Dissolution and Q value limits will be given within the monograph. This is a subsidiary title, which is also an official title for products that should comply with this monograph. As BP monographs can, in most cases, be applied to different product strengths, the disregard limit is usually based on the maximum daily dose for the drug substance and ICH guidelines. LIMITS In the chromatogram obtained with solution (1): the area of any peak corresponding to impurity C is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (3%); the area of any other secondary peak is not greater than half of the area of the principal peak in the chromatogram obtained with solution (2) (0.1%); the sum of the areas of any other secondary peaks is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.0%). The infrared absorption spectrum of the residue, is concordant with the reference spectrum of aspirin (RS 483). Any other secondary peak refers to any related substance peak in the chromatogram, apart from any impurities already specified in the limits section. The limit is measured against the peak area of the limiting solution, in this case solution (3). If the limit is described as 'the sum of the area of any secondary peaks' the areas of all related substances peaks that are detected above the disregard limit should be summed. Use 500 mL of a pH 4.5 buffer prepared by mixing 29.9 g of sodium acetate and 16.6 mL of glacial acetic acid with sufficient water to produce 10 litres at a temperature of 37°, as the medium.

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