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Solubility determination and characterisation of steroids

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Introduction: The pKa and logP of a compound affect its bioavailability and extent of action. The characterisation of properties of active pharmaceutical ingredients, such as solubility, aids in the development of analytical methods and formulations for finished dosage forms. To date, some of the physicochemical parameters of the steroids difluprednate and 6α9α-difluoroprednisolone are only characterised using computational methods.

Purpose: To experimentally determine the melting point and solubility of the selected steroids, difluprednate (DFPA) and 6α9α-difluoroprednisolone (DFP).

Method: The melting point of the selected steroids was investigated using a Griffin® melting point apparatus, and the result obtained was compared to the literature. An open-ended capillary was used to introduce the steroidal sample into the apparatus, and the temperature range over which the sample dissolved was recorded. The solubility of the steroids was assessed in different HPLC-grade solvents, namely water, methanol and acetonitrile. These solvents were selected since they are the most commonly used solvents in the analysis of active pharmaceutical ingredients. A set of stock solutions was prepared for each steroid in acetonitrile and methanol, respectively. The stock solutions were then sonicated using an IBX® Ultrasonic bath for 30 minutes and left overnight in the fridge. A set of dilutions was prepared by adding HPLC-grade water to methanol or acetonitrile at a ratio of 1:9, 3:7, 5:5, 7:3, and 9:1, respectively. The UV-spectroscopy SPECTROstar Nano (BMG LABTECH) was used to determine the solubility of the steroids. The stock solutions of each steroid were used to determine the wavelength which exhibits the best absorbance. The absorbance of the pure solvents was determined to eliminate interferences. A quartz cuvette was used for the analysis, and each sample was analysed in triplicates, and the average absorbance was calculated. Spectrograms were plotted in Excel, and the solubility was determined from the area under the peak.

Results: The melting point of difluprednate was found to be 188-189°C, and that of 6α9α-difluoroprednisolone was found

to be 210-220°C. The wavelength which provided the best absorbance was 242nm. The maximum UV absorbance when analysing the diluted solutions of DFPA and DFP were 6.815 Au and 3.359 Au, respectively. These results indicate that the highest solubility of difluprednate was achieved when dissolved in a methanol and water mixture at a ratio of 1:9 with a solubility of 0.72mg/ml. The highest solubility of 6α9α-difluoroprednisolone was 1.92mg/ml. This solubility was observed when the steroid was dissolved in a mixture of acetonitrile and water at a ratio of 1:9 respectively.

Conclusion: The melting point of the analysed steroids was found to be in accordance with values found in the literature. The experimental determination of the solubility of the analysed steroids will contribute towards improved analytical method development.

Mapping of temperature and humidity fluctuations in an emergency medical setting of ambulance service: A prospective observational study in Qatar

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Introduction: Paramedics working in emergency medical settings (EMS) are required to administer life-saving medications to patients routinely. Typically, these medications experience undocumented fluctuations in environmental conditions, including temperature and humidity (T/H), which may lead to the degradation of the drug and harm to the patient. In a country like Qatar, known for its high temperatures and relative humidity, the conditions to which the paramedic medications are exposed are yet to be documented and require careful assessment. This study aims to map the T/H in Hamad Medical Corporation Ambulance Service (HMCAS) vehicles, as well as identify the magnitude and reasons for excursions in the mean kinetic temperature (MKT).

Method: In this study, six HMCAS Charlie unit vehicles, each with three temperature and humidity data loggers, were used to assess the T/H fluctuations experienced by the ambulatory medications. Two of the data loggers were placed in two paramedic bags stored at the back of the unit, while the third data logger was mounted on the unit's metal net. T/H readings were recorded at 10-minute intervals over a year. Data was then extracted from the loggers, analysed using Python, and subjected to statistical analysis.