

# Solubility Determination and Characterisation of Steroids

Giulia Baluci<sup>1</sup>, Everaldo Attard<sup>2</sup>, Nicolette Sammut Bartolo<sup>1</sup>, Anthony Serracino-Inglott<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

<sup>2</sup>Rural Sciences and Food Systems, Institute of Earth Systems, University of Malta

## INTRODUCTION

The pKa and logP of a compound affect its bioavailability and extent of action. Characterisation of properties of APIs, 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 6 $\alpha$ 9 $\alpha$ -difluoroprednisolone are only characterised using computational methods.

## AIMS

To experimentally determine the melting point and solubility of the selected steroids, difluprednate (DFBA) and 6 $\alpha$ 9 $\alpha$ -difluoroprednisolone (DFP).

## METHOD

### Phase 1: Melting Point Determination

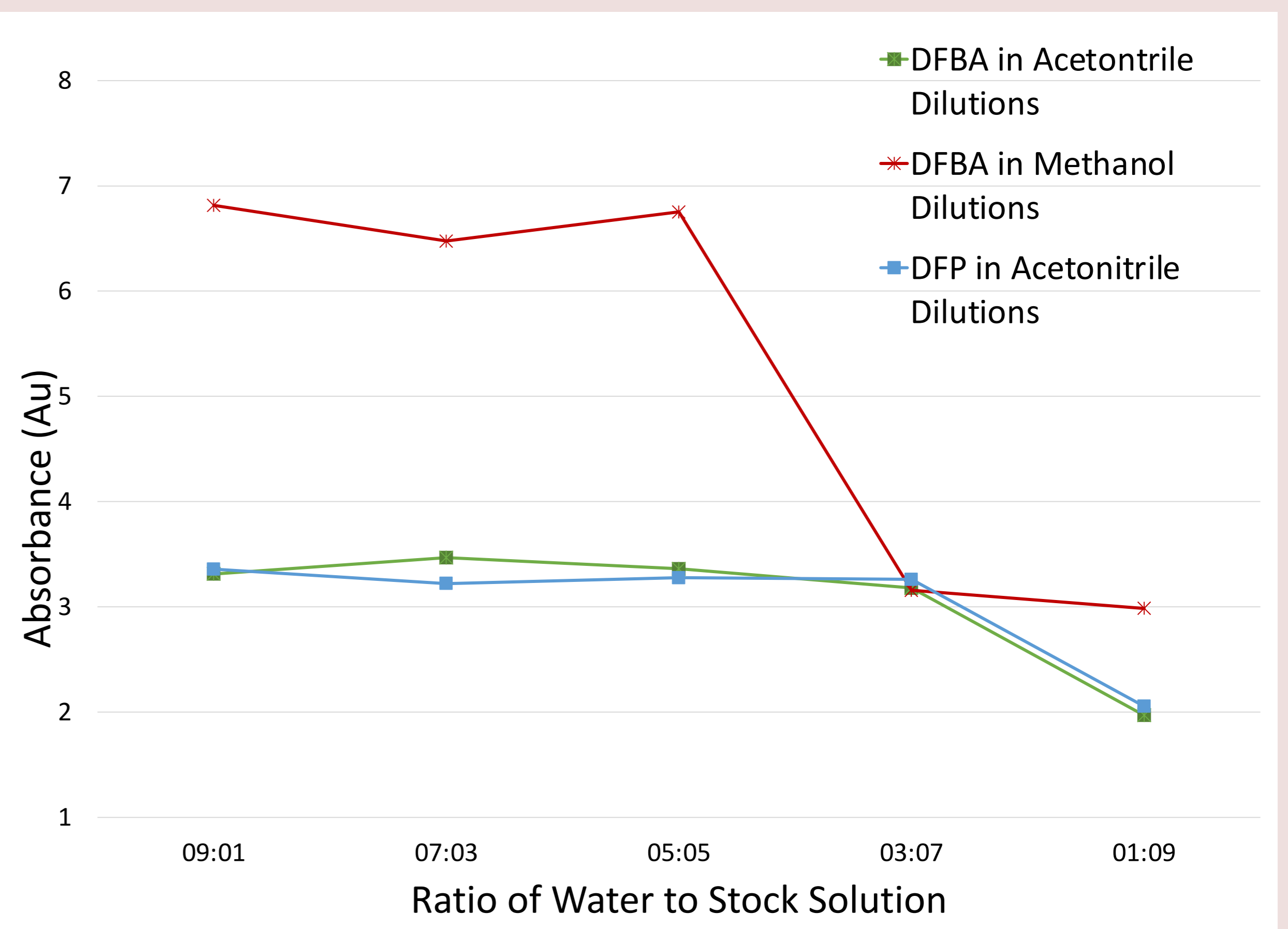
- Melting point was determined using a melting point apparatus
- Results obtained were compared to literature

### Phase 2: Solubility Testing

- Steroidal stock solutions were prepared in acetonitrile and methanol
- Dilutions were made by adding water to the stock solutions at a ratio of water:organic solvent of 1:9, 3:7, 5:5, 7:3 and 9:1, respectively
- Each concentration was analysed using UV-spectroscopy to determine the wavelength at which there is highest absorbance
- UV spectra were plotted, and the solubility determined using the area under the peak

## RESULTS

1. The melting point of DFBA was found to be 188-189°C and that of DFP was 210-220°C.
2. The optimal wavelength of absorbance was determined to be 242nm for both steroids.
3. The maximum UV absorbance achieved for the dilutions of DFBA and DFP were 6.815Au and 3.359Au, respectively.
4. The highest absorbance achieved for DFBA was in methanol and water at 1:9, with a determined solubility of 0.72mg/ml, while that of DFP was in acetonitrile and water mixture at 1:9, with a determined solubility of 1.92mg/ml.



Absorbance achieved for DFBA and DFP in different dilutions

## CONCLUSION

The melting point of the analysed steroids and the optimal wavelength were found to be in accordance with values found in literature<sup>1,2,3</sup>. The experimental determination of the solubility of the analysed steroids will contribute towards improved analytical method development.

## REFERENCES

1. Difluprednate. Reaxys. ID 11341627
2. Difluoroprednisolone. Reaxys. ID 37936916
3. Prajapati M, Loftsson T. Stabilization and solubilization of difluprednate in aqueous cyclodextrin solution and its characterization for ophthalmic delivery. Journal of Drug Delivery Science and Technology. 2022;69:103106. Doi: 10.1016/j.jddst.2022.103106.