THE DEVELOPMENT AND UNDERSTANDING OF A CHLORHEXIDINE MOUTHWASH FORMULATION

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INTRODUCTION

Corsodyl (chlorhexidine digluconate 0.2 %) an anti-bacterial oral rinse that reduces the formation of dental plaque and is used for the treatment and prevention of gingivitis (inflamed, swollen or bleeding gums). This mouthwash is a licensed medicine intended for patients with symptoms of gingivitis or advised by a dental healthcare professional.

Figure 1: *Range of Commercial Product.*

AIMS

The aim of this project was to determine an optimised formulation for the purposes of building further understanding of the ingredients of the original formulation. To do this, the surfactant type and level (%w/w), flavour agent type and level (%w/v) and chlorhexidine digluconate level (%w/v) was varied.

TECHNIQUES USED

Name of Test	Purpose of Test
Appearance	Assigning a subjective value for the opacity of the sample
Turbiscan	A Static Multiple Light Scattering technique that assigns an objective value to the % transparency of the sample
Foam Test	Testing Foam build up and Foam decay to foresee any issues with factory scale production.
Zetasizer	A Dynamic Light Scattering technique which calculates the distribution of micelle size in solution
pH	Testing the stability of the formulation sample
HPLC	A Chromatography technique which calculates assay values of chlorhexidne and its impurities within solution

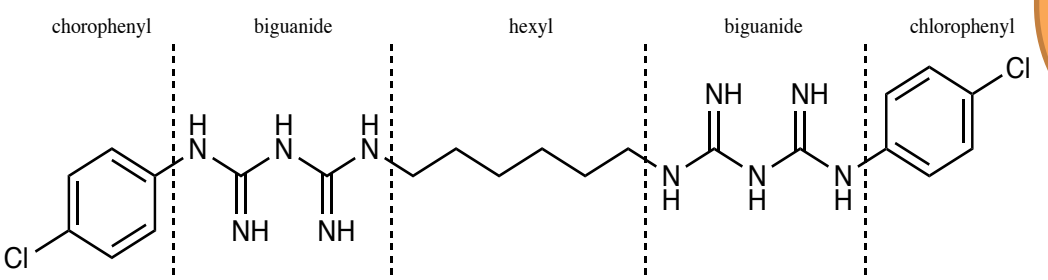

Figure 3: *Chlorhexidine Structure.*

KEY RESULTS

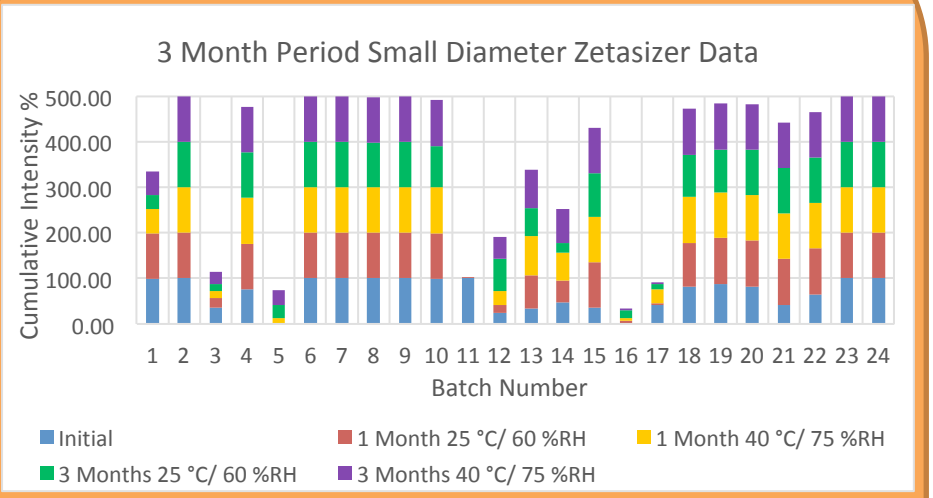

Figure 2: *Small Diameter Zetasizer Column Graph.*

Batches with a high surfactant concentration, the flavour agent can be increased or reduced with minimal effect on micellular size: with data sets showing 100 % intensity for small diameter micelles with no diameter increase over the 3-month period. This is due to the surfactant being at a high enough concentration to fully encapsulate all the flavour agent present into small micelles increasing the formulations stability.

CONCLUSIONS

The most desirable formulation was found to include: chlorhexidine digluconate level at 0.2 %w/v, high surfactant to low flavour agent ratio (with the surfactant being at 1.2 %w/w and the flavour agent being interchangeable) and the surfactant type being RH 40. This results in a transparent solution with a relatively high pH and high chemical and physical stability. This optimised formulation with its high surfactant concentration is in line with factory manufacturing practicalities.

FUTURE WORK

- Testing the effectiveness of the antimicrobial properties of a number of optimised formulations.
- The stability period will be extended to 12 months to further test the stability and simulating a worst-case scenario for further understanding.
- The robustness of the formulations will be tested by scaling up to the manufacturing process to assess the practicality of the altered formulations.