

FINAL REPORT

Three Month Clinical Evaluation of the Contamac GM3 Soft Contact Lens

STUDY NUMBER: GM3X-1901-XXXX
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A INTRODUCTION

The GM3 soft contact lens material is a copolymer containing glycerol methacrylate (GMA). The material has been manufactured by Contamac Ltd in blank form and supplied to various contact lens manufacturing laboratories who, in turn, have marketed a variety of soft contact lenses within the European Community.

A.1 Objectives

- i. To evaluate the clinical performance of the GM3 soft contact lens.
- ii. To compare the clinical performance of the GM3 soft contact lens with a currently marketed soft contact lens (Cantor & Nissel Hydrofit 55).

A.2 Statement Of Compliance

Sixty-one (61) subjects were enrolled in the study. Of these 38 subjects (62%) wore the test lens (GM3), 20 subjects (33%) wore the control lens (Hydrofit 55) and the remaining 3 subjects (5%) were not dispensed lenses.

A.3 Study Design and Population

Sixty-one (61) subjects were enrolled in the study, of whom 58 were dispensed lenses.

This was a three-month, open-label, bilateral, randomised, daily wear study. Approximately two-thirds (38/58) of the subjects dispensed wore the Contamac GM3 soft lens in both eyes while the other 20 (34%) subjects wore control lenses.

B MATERIALS AND METHOD

B.1 Study Lenses

Study lenses were available in the following parameters:

Test Lenses: Contamac GM3 soft contact lenses

Sphere Power: +8.00 to -8.00D in 0.25D increments
Base Curve: 8.50mm
Diameter: 14.6mm
Lot #: OIF598

Control Lenses: Cantor & Silver Hydrofit 55 (Benz 55G) soft contact lenses

Sphere Power: +8.00 to -8.00D in 0.25D increments
Base Curve: 8.50, 8.80mm
Diameter: 14.5mm
Lot#: LR26, LR27

Test and control lenses were replaced on a scheduled monthly basis.

B.2 Summary of Safety and Effectiveness

In general, there were no differences between GM3 and Hydrofit 55 lenses in respect of biomicroscopy findings, symptoms or vision safety measures. Where statistically significant differences occurred, on average, these were a fraction of a grade unit and tended to be evident at a single visit only. These differences, therefore, cannot be regarded as clinically relevant findings. The two lens types can, therefore, be considered as being clinically equivalent in terms of safety and effectiveness.

C CONCLUSIONS

- i. GM3 material contact lenses performed well and are safe and effective over a 3-month period.
- ii. GM3 and Hydrofit 55 lenses perform equally well over a 3-month period contact lens wear.