

## Vitamin E as an Antioxidant in Implants Concentration Determination in GUR® / Alpha-Tocopherol Blends

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**INTRODUCTION:** Alpha-tocopherol stabilization of GUR® UHMWPE implants for total joint replacements is one of the major trends in current development efforts. A large number of scientific papers have been published on this subject and the commercialization process of alpha-tocopherol containing implants has already started.

The desired concentration ranging from trace amounts like e.g. 200 ppm to high levels like e.g. 5000 ppm has been discussed for quite some time. At the same time the concentration determination in UHMWPE powder as well as in the final implant has been a subject of research activities.

**METHODS:** The described determination method for alpha-tocopherol contained in GUR® UHMWPE powder can be subdivided into different steps: extraction, HPLC separation and UV detection.

For the extraction step a small amount of alpha-tocopherol containing material is boiled with methanol under reflux for a few hours. The solution is then filtered over a 0.45 µm filter. For the determination of the extracted alpha-tocopherol an analytical HPLC system with UV detector was employed. Zorbax Eclipse XDB-C8 (or comparable) columns were used at 50 °C and the eluent was a 95 / 5 methanol / water mixture. The vitamin E concentration is determined at the 291 nm absorption band.

**RESULTS:** For the validation of the UV detection, solutions with different alpha-tocopherol concentrations ranging from 0.5 to 1000 ppm were used.

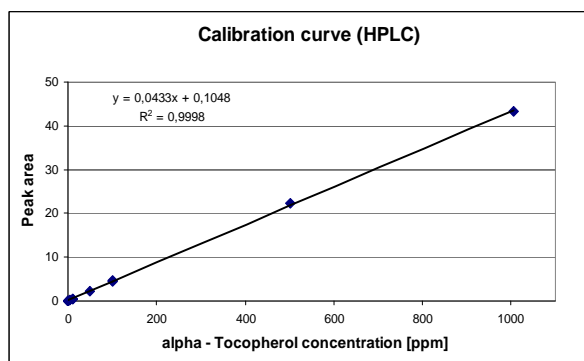


Figure 1: Calibration curve for UV detection

The graph illustrates the excellent linear correlation between the vitamin E concentration and 291 nm peak area. The lower limit for the concentration determination was found to be 1 ppm while the detection limit is 0.5 ppm.

In a second step the retrieval of the extraction process was tested. Different amounts (5 to 50 ppm) of vitamin E were added to GUR® 1020 powder already containing 500 ppm. The additive was then extracted by the method, described and an average retrieval rate of 93% was found.

Reproducibility of the method was tested by measuring 27 identical samples (Figure 2). As an average 961 ppm of alpha-tocopherol were found in the powder sample. The standard deviation of the measurement is 35.6 ppm (3.7 %).

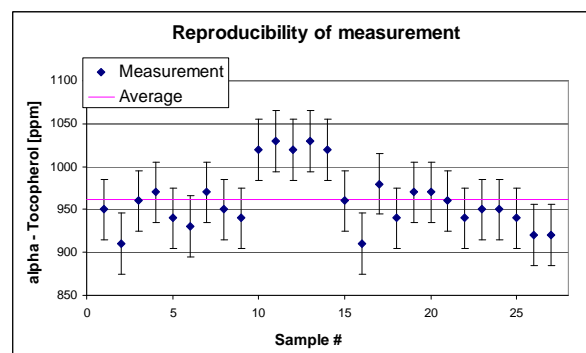


Figure 2: Reproducibility assessment

**DISCUSSION & CONCLUSIONS:** The described method shows a new approach to reliably and accurately determine alpha-tocopherol concentrations in UHMW-PE (GUR®) powder especially for low concentration ranges.

Tests with molded sheets have been started recently; the first results look very promising so that the method can be applied to semi-finished goods, also. The loss of alpha-tocopherol due to heating during compression molding or any post treatment can be checked with this method, too.