Project Specification – Stability and sterility of insulin in prefilled Daily Dose™

Background

Daily Dose™ insulin injection system consists of syringes for single use designed for self-injection of insulin by people with diabetes. The product is a Class IIa medical device according to rule 6 of MDD 93/42/EEC, Annex IX as amended by the Directive 2007/47/EC, and has been CE-marked.

The product is patented in several countries and internationally patent-pending, and differs from conventional insulin syringes as it is pre-fillable, portable, and discreet in usage due to its small size.

As insulin is a protein that loses its efficacy with time and temperature differentiation, it is best kept in a temperature-controlled environment, such as in the home. Instead of carrying the entire month’s supply of insulin with the user at all times in an insulin pen or vial, Daily Dose™ is designed so that the user only needs to carry the doses needed for the day’s usage, and leave the supply of insulin at home. This is achieved through prefilling three syringes with the user’s choice of meal-time insulin, and putting them into the triple-holder carrying case, to be used during the day. After injections, the carrying case also acts as a temporary disposal for the used syringes.

Objective

One of the main advantages of the Daily Dose™ is the fact that it is portable when prefilled. Reference material has proven that the efficacy and sterility of the insulin in a drawn-up state in a plastic insulin syringe (prefilled) can be maintained for certain period of time depending on the temperature environment. A similar study is now needed with the actual Daily Dose™ syringes, to find out how the stability and sterility of different kinds of insulin drawn-up in Daily Dose™ syringes vary with:

- Time
- Temperature
- Other possible environmental factors

Methodology

To achieve the objective of this study, an experiment needs to be devised to test several different types and brands of insulin in a drawn-up state in vitro, with test results that can be statistically significant. The variables are at least two; time and temperature, and possibly others as well, to be decided in consultation with Insulution AB. The company shall provide the necessary testing material of both Daily Dose syringes and different brands of insulin.
Project time plan

This study is subject to a thesis report at University degree level (30hp), with the following approximate time plan.

- Concluding project plan: 1 – 2 weeks
- Pilot study: 2 – 4 weeks
- Data collection: 8 – 10 weeks
- Analysis and report writing: 4 – 6 weeks

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**Remuneration**: Aside from expenses of lab material, an allowance is also included in the partaking of this project.