Product Design Specifications

EWH Liquid Medication Delivery System

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Project Description

The purpose of this device is to seal bottles of nevirapine, and to allow pharmacy technicians to sterilely dispense 0.6mL doses of nevirapine into foil medication packages developed by EWH.

Design Requirements

A. Physical and Operational Characteristics

1. **Accuracy and Reliability**
   - The device must dispense within ± 0.05mL of 0.6mL of nevirapine (Feest, Maharaj, Mogen, Cira, 2008).
2. **Life in Service**
   - The device must accurately deliver up to 4000 doses, thus dispensing the maximum number of doses contained in a nevirapine bottle (Feest et al., 2008).
   - The device must remain in operation for a minimum of 6 months, which is the maximum shelf life of an open nevirapine bottle (Feest et al., 2008).
   - The device must have a shelf life of at least 5 years (Feest et al., 2008).
3. **Operating Environment**
   - The device must be able to be dropped from a minimum of 2 meters (Feest et al., 2008).
   - The device must be able to withstand temperatures ranging from -10°C to 50°C (Feest et al., 2008).
   - The device must withstand 0 to 100% humidity.
   - The operating environment may be contaminated with dirt, dust, insects, and aerosolized contaminants. The device must maintain the sterility and purity of the medication before, during, and immediately following use.
4. **Ergonomics**
   - The forces required to operate the device should be low enough that a minimum of 98% of people over 13 years old can use the device.
5. **Size**
   - The device must seal the nevirapine bottle that is currently used. "Nevirapine is patented by Boehringer Ingelheim (BI), and they have one type of bottle that all nevirapine is distributed in" (Cooper, 2009).
6. **Weight**
   - The device must weigh less than an empty nevirapine bottle.
7. **Materials**
   - Though not an essential requirement, the device's component materials ought to be available in developing nations; specifically, in rural regions of Peru, The Congo, and India.

B. Production Characteristics

1. Production

- The device will be mass produced, and preferably be assembled from parts available in developing nations.

2. Cost

- The device must cost less than $2 USD (Feest et al., 2008).

C. Miscellaneous

1. Quantity

- The device will be mass produced.

2. Customer

- The device will be used by pharmacy technicians in developing nations.

3. Patient-related Concerns

- If the design is accepted by EWH, then EWH will own all of the IP rights pertaining to the device, and the device will be placed in the public domain (Feest et al., 2008).

4. Competition

- A variety of liquid medication delivery devices are available, including one produced by BI, but are too expensive for widespread use in developing nations (Feest et al., 2008; Cira, 2009).

References

Cira, N. Sept. 4, 2009. Personal Communication.

Cooper, J. 2009. "RE: Senior Design Project Update." Email to the authors.

Feest, A., Maharaj, V., Mogen, B., Cira, N. 2008. "Product Design Specifications." Accessed Oct. 1, 2009, at <http://homepages.cae.wisc.edu/~bme300/ewh_f08/secure/reports/Product_Design_Specification.pdf>