

Testing the Materials Used in a Needle-Free Injector

A universal material tester has proved invaluable during the development of one company's needle-free injection system.

The system

Materials testing plays an important role in product development, materials acceptance and quality-control programmes for medical devices. For example, materials-testing instruments have been used for testing the flexural characteristics of tracheal tube introducers and the firing load and valve breakdown load of pressure canisters in one-shot, metered-dose inhalers. Device manufacturer, PowderMed Ltd, has made extensive use of a 2.5-kN LRX single-column universal material tester (Lloyd Instruments) for testing parts of its PMED single-use, needle-free injection system (Figure 1). The system delivers therapeutic and prophylactic deoxyribonucleic acid (DNA) vaccines into

the skin in a dry-powder formulation of gold-coated particles, which have a mean particle diameter of 1–3 μm . These particles are used as the plasmid DNA carrier because they are inert and have the appropriate density needed to deliver the vaccine directly into the target epidermal antigen-presenting cells. The powdered vaccine is contained in a cassette that is sealed by a thin polymer-film membrane. The cassette is loaded into the body of the system during the final product assembly and packaging process. A self-contained microcylinder containing pressurised helium gas is also housed in the unit. Depressing a button on the unit breaks the tip of the cylinder and releases the gas. This ruptures the cassette membrane and forces the particles from the cassette through the nozzle and into the epidermal layer of the skin at high velocity.

- the force required to penetrate the membrane films to ensure that the pressurised gas creates the same ballistic performance for each delivery device
- the load required to break the tip on the microcylinder to release the pressurised gas
- the load required to assemble and disassemble a cassette.

All the tests were performed on the LRX instrument and were based on extension or compression testing, whereby an increasing load is applied to the component under test via a special probe until a break or limit is reached. Special jigs were manufactured to hold the different components. The PC-controlled instrument is equipped with NEXYGEN MT materials test and data-analysis software and Ondio application builder software. The general purpose compression test routine in the NEXYGEN software was used to determine the load required to press the actuation button on the system (Figure 2). Figure 3 shows the resulting plot of deflection as a function of the load applied. The rapid drop in the graph indicates the load required to activate the button. Figure 4 shows the arrangement for separating the cassette components.

Tests on probe penetration through cassette films and the load required to

Figure 1: Schematic diagram of the needle-free injector.

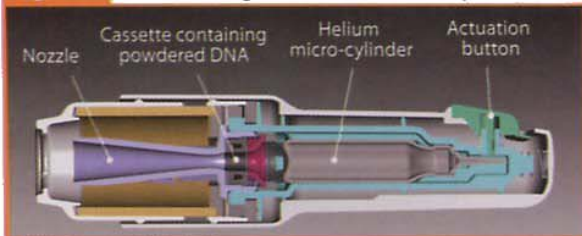


Figure 2: Assembly for testing the load required for button activation. The system is held in position using the custom-designed jig and force is applied to the actuation button.

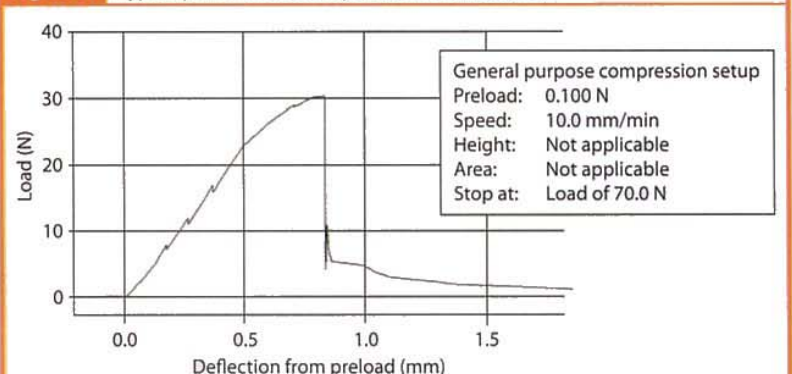


Test methods

A number of test methods have been developed to evaluate the critical components of the system. These include tests to evaluate

- the load required to press the actuation button on the injector to ensure that it cannot be accidentally depressed and that it is not too "stiff" to operate

Figure 3: Typical plot of the load required to actuate button.



disassemble a cassette are nonstandard and were set up using the application builder software. Figure 5 shows a typical plot for probe penetration through the cassette films. The cassette has two films, one on the body component and one on the lid. Both of these are ruptured during injection.



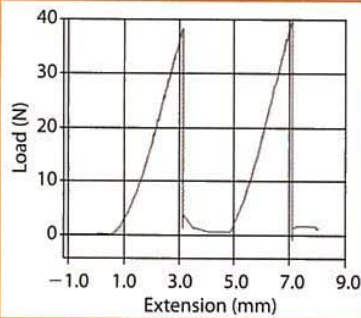
Figure 5 shows two peaks. The first is for cassette body component film and the second is for the lid. It is necessary to have similar rupture characteristics for both films on the cassette to ensure the correct ballistic properties are achieved for drug delivery.

Benefits for product development

The cassette assembly and disassembly test was used in the cassette design and development phase; the button activation test has been employed to refine the injection moulds used to produce the

components. There is, however, scope to extend the testing into quality-control applications. Testing of the polymer membrane is performed on the as-received membrane material, but is not yet used for routine testing in situ on cassettes. This is because the location of the probe relative to the cassette is critical and further refinement of the jig arrangement is required. The test for determining the force required to break the microcylinder tip has been used to establish ergonomic features of the product design and used in component quality control.

Figure 5: Typical plot for probe penetration through cassette films.



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