Nemaura Pharma provides end-to-end turnkey solutions for drug delivery through the skin using its proprietary platform technologies. Its two lead technologies are the Memspatch® microneedle system and Micropatch™ skin insertion platform. In combination, these technologies offer versatile topical or transdermal delivery platforms for a large range of molecules, including biologics.

Improving patient compliance, reducing side-effects, and enhancing effectiveness of therapy by maintaining constant drug plasma levels are leading to an increasing number of drug companies turning to transdermal drug delivery platforms both for existing molecules as well as new chemical entities and biologics.

**Nemaura’s Key Objectives:**
- Improve patient compliance
- Remove operator dependence
- Make devices intuitive to use
- Simplify production processes
- Keep costs down
- Provide versatile platforms for small molecules through to biologics
- Provide efficient end to end turnkey solutions to clients

**Memspatch® Microneedle Skin Delivery Platform**

The memspatch® is a versatile platform for the delivery of small molecules as well as biologics in a reproducible, almost operator independent manner. The platform includes a device that acts as an applicator for administering almost any microneedle type patch to the skin. Microneedles are needles whose length is in the hundreds-of-microns range, which are produced from a wide variety of materials including polymers, metals, and the drug formulation itself.
Microneedles are traditionally inserted into the skin either using high impact mechanical or pneumatic actuator devices, or by depressing into the skin using the thumb. These methods suffer from the issues of operator training and person-to-person variability in dosing due to inaccurate operation or uneven pressure being applied to the patch. Furthermore the high impact devices can potentially lead to trauma of the skin, and breakage of the tips of the needles, maintaining the sharpness of which is crucial to ensure painless skin penetration. Moreover these are generally large devices that are bulky to carry around and complex thus costly to produce and supply.

The Memspatch® is unique and possibly the most effective means of obtaining reproducible and consistent dosing with microneedles, using a minimal-impact or ‘zero-impact’ technique.

As shown in Figure 1a, the applicator device consists of a patch that may be self-adhesive with a compartment that retains the drug-loaded microneedle patch. The drug-loaded patch is loaded into the device during manufacture and sealed away from the patient (Figure 1b), thus preventing any possibility of breakage of the needles or accidental injury to the patient.

Figure 1: Memspatch® allows ‘zero-impact’ application of microneedles to the skin for topical or transdermal application.

Figure 2: Memspatch® in place, applied on the forearm.
Once the Memspatch® is applied, the patch compartment is slid across the skin, and gently glides across (Figure 1c). As it glides, the internal mechanism of the Memspatch® (schematic shown in Figure 1d) eases the microneedles over the skin one row at a time, ensuring 100% of the needles gradually ease into the skin with virtually zero impact force and without the inconsistencies of high impact devices.

Figure 2 shows the patch in place on the arm. Nemaura offers this system either as a platform for use with microneedle patches produced by their clients, or with Nemaura’s own microneedle formulation produced using a readily scalable process that does not require costly installations.

This particular formulation may be used for both topical administration as well as some systemic products. The patch may be retained on the skin for minutes or several hours where required and is produced cost-effectively using conventional patch manufacture facilities.

Skin permeation studies using diclofenac sodium in Nemaura’s formulation showed a 40-fold increase in the amount of drug administered compared with a market leading gel, without leaving any visible signs of skin irritation, and an administration/patch skin application time of less than one minute; that is, the patch was removed immediately after administration in this instance.

**MICROPATCH™ SOLID DOSE SKIN INSERTION PLATFORM**

The Memspatch® technology described above provides an avenue for the delivery of a range of molecules primarily intended for deliv-

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ery over a sustained period of time. One of its key limitations is that many molecules requiring skin delivery will not have the correct physicochemical properties that allow them to be formulated into microneedles with the required physical strength, or allow them to be coated on to the surface of microneedles for delivery to or via the skin.

Micropatch™ overcomes these limitations allowing almost any molecule in solid or semi-solid form to be gently inserted into the skin to the desired depth – in conjunction with super-sharp stainless steel needles.

The actuator is a single-component produced by injection molding a single piece of plastic, thus cost effective to produce as a single use disposable unit (see Figure 3).

Micropatch™ can be used for a single drug or multiple drugs simultaneously using multiple needles on a single device. This is achieved using a single pressing motion and a disposable device.

Needle length can be varied from hundreds of microns, that would be pain free, or several millimeters in length for deeper depot delivery of drug ‘packages’. The drug packages may be formulated as spheres in the diameter range of tens to hundreds of microns, making it easy to administer precise doses, effortlessly and mostly painlessly.

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The device works on the principle of the microneedle, in that sharp small diameter stainless steel needles effortlessly pierce the skin, and can be pain free depending on the depth of penetration. This insertion is then followed by the insertion of a defined dose of the drug in a microsphere, or other structure with defined dose, ensuring 100% of the dose loaded is delivered instantly. The sequence of steps for drug delivery are shown in Figure 4.

Formulations can be adjusted to provide very rapid onset of absorption and action, or sustained delivery over hours, and days, or weeks where required. The needles can automatically retract within the device thus preventing sharps injuries or damage to the device on storage and transport.

The applications of these technologies are broad and range from small molecules to peptides and proteins, and vaccines. They provide means for enhancing stability by eliminating the cold chain, and improving patient compliance. They enable self-administration and provide a robust means for minimally invasive instant delivery of drugs via the skin.

Nemaura Pharma already has global license agreements with pharmaceutical companies for some of its technology platforms. Nemaura is actively seeking to broaden the list of partnerships and collaborations where molecules, which may otherwise suffer from inadequate dosing or dosing methods to which patients are averse, can be simply and effectively delivered by gently gliding solid and semi-solid micro-doses accurately and consistently into the skin.