WE CLAIM:

1. A microneedle array patch (100) for drug delivery comprising:
(a) a backing layer (103);
(b) a plurality of dissolvable polymeric microneedles (102) fixed to said backing layer (103), said polymeric microneedles (102) being made up of polyvinyl alcohol (PVA) and gelatin, said polymeric microneedles (102) being fixed to and extending from an adhesive surface provided on the backing layer (103); and
(c) drug loaded nanocarriers (101) entrapped within a matrix of said polymeric microneedles (102) for delivery by said polymeric microneedles (102) into skin; wherein said drug loaded nanocarriers (101) are selected from the group consisting of lipid nanocarriers or polymeric nanocarriers.

2. The microneedle array patch (100) as claimed in claim 1, wherein the backing layer (103) is made up of polyester, cellulose acetate, polyvinyl chloride, fiber reinforced plastic (FRP) sheets, polypropylene, polyethylene, ethylene-vinyl acetate copolymer, polyurethane, ethyl cellulose, fabrics, non-wovens, foam, co-extruded multilayer polymeric films, in an intact or perforated form.

3. The microneedle array patch (100) as claimed in claim 1, wherein the adhesive surface comprises a pressure sensitive adhesive disposed on one side of backing layer (103) to facilitate adhesive attachment of the backing layer (103) with the polymeric microneedles (102).

4. The microneedle array patch (100) as claimed in claim 4, wherein the pressure sensitive adhesive (PSA) is selected from the group consisting of silicones, polyacrylate adhesives, methacrylate polymers and copolymers, polyisobutylenes polysiloxanes, polyisoprene, polybutadiene, and styrenic block polymers.

5. The microneedle array patch (100) as claimed in claims 1 and 3, wherein the polymeric microneedles (102) are separated from the backing layer (103) after insertion into the skin due to the hydrophilic – hydrophobic interaction between the polymeric microneedles (102) and the adhesive surface of the backing layer (103).

6. The microneedle array patch (100) as claimed in claim 5, wherein the hydrophilic-hydrophobic interaction is a result of contact angle difference between the polymeric microneedles (102) and the adhesive surface of the backing layer (103) and wherein said contact angle difference is greater than 10°.

7. The microneedle array patch (100) as claimed in claim 1, wherein the polyvinyl alcohol (PVA) and gelatin are present in the ratio of 2:1.

8. The microneedle array patch (100) as claimed in claim 1, wherein the lipid nanocarriers are selected from the group consisting of soya phosphatidylcholine (SPC), oleic acid, hydrogenated soya phosphatidylcholine (HSPC), Di-stearoyl phosphatidylcholine (DSPC), Dimyristoylphosphatidylcholine (DMPC), Di-oleoyl phosphatidylcholine (DOPC), 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine (POPC), 1,2-distearoyl-sn-glycero-3-phosphoglycerol (DSPG), 1,2-dioleoyl-sn-glycero-3-phosphoethanolamine (DOPE), egg lecithin, soya lecithin, egg phosphatidylcholine, phosphatidylethanolamine (PE), phosphatidylserine (PS), phosphatidic acid (PA), phosphatidylinositol (PI), phosphatidylglycerol (PG), and cardiolipin (CL).

9. The microneedle array patch (100) as claimed in claim 1, wherein the polymeric nanocarriers are selected from the group consisting of polycaprolactone (PCL), polymethylmethacrylate (PMMA), poly lactic acid (PLA), polyglycolic acid (PGA), polylactide-co-glycolic acid (PLGA),

polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), carboxymethyl cellulose (CMC), polyethylene (PE), and polypropylene.

10. The microneedle array patch (100) as claimed in claim 1, wherein the drug is selected from the group of contraceptive agents, anti-inflammatory agents, anti-psychotic agents, anti-diabetic agents, local anesthetics, narcotics, psychotropic agents and anticoagulant medications.

11. The microneedle array patch (100) as claimed in claim 10, wherein the drug is levonorgestrel, estradiol, ethinylestradiol, progestins, and ormeloxifene.

12. The microneedle array patch (100) as claimed in claim 1, wherein the patch (100) is tuneable for sustained release and delivery of drug from 1 week to 24 months.

13. A method of producing the microneedle array patch (100) comprising:

a) preparing a master mould which replicates the required microneedle array configuration;

b) preparing a secondary mould using soft-lithography of an elastomer wherein the secondary mould has the same surface contour as the master mould;

c) curing the elastomer and separating the secondary mould from the master mould;

d) preparing and mixing a base polymer matrix (102) with drug loaded nanocarriers (101);

e) pouring the base polymer matrix (102) along with the drug loaded nanocarriers (101) onto the secondary mould and centrifuging the same to ensure homogenous solution enters to all the pores;

f) transferring the secondary mould centrifugally filled with base polymer matrix (102) solution containing drug loaded nanocarriers (101) into a

sterile container and drying said solution for 8 hours to 48 hours at 20 °C to 40 °C with a relative humidity ranging between 45% to 55%;

g) transferring the microneedles onto a backing layer (103); wherein one side of the backing layer has a pressure sensitive adhesive applied for attachment of the backing layer (103) with the polymeric microneedles (102) to form the microneedle array patch (100).

14. The method as claimed in claim 13, wherein the master mould is prepared by techniques selected from the group consisting of EDM (electro-discharge machining), 2 photon lithography, laser writing, and masked lithography.

15. The method as claimed in claim 13, wherein silicone elastomer is used to prepare the secondary mould.

Dated this 20 Day of April 2020

Indian Institute of Technology Bombay
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