Transdermal drug delivery technology

OBJ LIMITED

PRESS RELEASE

Tuesday, 6 December 2005

FOR IMMEDIATE RELEASE

PRESENTATION TO THE AUSTRALASIAN PHARMACEUTICAL SCIENCE ASSOCIATION ANNUAL SCIENTIFIC MEETING

OBJ Limited (ASX:OBJ) is pleased to make available the materials to be presented by Sarika Namjoshi BSc(Hons) of Curtin University's Drug Development Department to the annual scientific meeting of the Australasian Pharmaceutical Science Association.

The invitation to present was extended jointly by the Australasian Pharmaceutical Science Association and the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

The annual meeting commenced in Melbourne on 4 December 2005 and closes on 7 December 2005.

- END -

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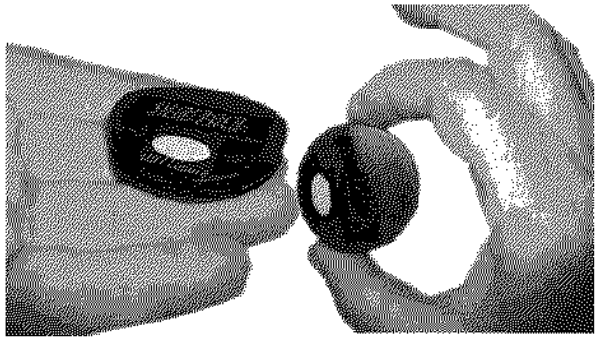
Background to the Announcement

OBJ Limited is a drug delivery company, specializing in electronic "drug patch" technologies that allow drugs, vaccines, therapeutic agents and cosmetic compounds to be delivered more effectively and more efficiently through-the-skin.

The OBJ Dermaportation system has been shown to manage and control the transdermal delivery of a broad range of drugs and therapeutic agents ranging from small difficult molecules such as Caffeine, through to large macro-globular proteins drugs such as vaccines.

OBJ's technology has been independently proven in both in-vitro and in-vivo studies and can manage a broader range of molecular sizes, structures and valencies than other active or passive drug delivery systems.

OBJ has been successful in managing the through-the-skin delivery of drugs used in the inflammation, pain, cancer and cosmetic fields.



OBJ's technology is low cost, and can be incorporated into reusable drug patches, (as illustrated) disposable single use drug patches and in a range of packaging systems for OTC and retail use.

Sustainable Benefits

Low cost and controlled through-the-skin delivery of drugs, hormones, vitamins, vaccines, anti-bodies and anti-aging molecules has long been the desire of the pharmaceutical industry. It would provide economic, safety and efficacy benefits to the pharmacology, medical, veterinary and cosmetic industries. Side effects could be reduced by localized delivery and programmed delivery rates. Needle stick injuries and needle disposable problems could be eliminated while the reduction in the level of skill required for application could significantly reduce total cost of many health programmes. These clear commercial benefits may only be achievable if the skin's natural barrier effect can be overcome.

OBJ is the first company to create a broad spectrum through-the-skin delivery system that is kind to the skin, completely reversible, yet can handle drugs range from the small difficult molecules up to the largest and most complex proteins and anti-bodies. OBJ manages an extensive IP portfolio and prosecutes patent applications throughout the world.

Independence of Results

OBJ contracts its drug and technology testing programs to independent and respected organisations, such as Western Australian Biomedical Research Institute, Western Australian Institute for Medical Research, Curtin University of Technology and Murdoch University. The high level of independence and international accreditation means that the results attributable to OBJ's proprietary technology can be published and presented at major medical and scientific conferences and forums.

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HPLC ASSAY FOR 5–AMINOLEVULINIC ACID AND ITS APPLICATION TO ASSESSMENT OF SKIN PENETRATION

Sarika Namjoshi, Rima Caccetta,
Jeff Edwards and Heather Benson

Curtin University of Technology

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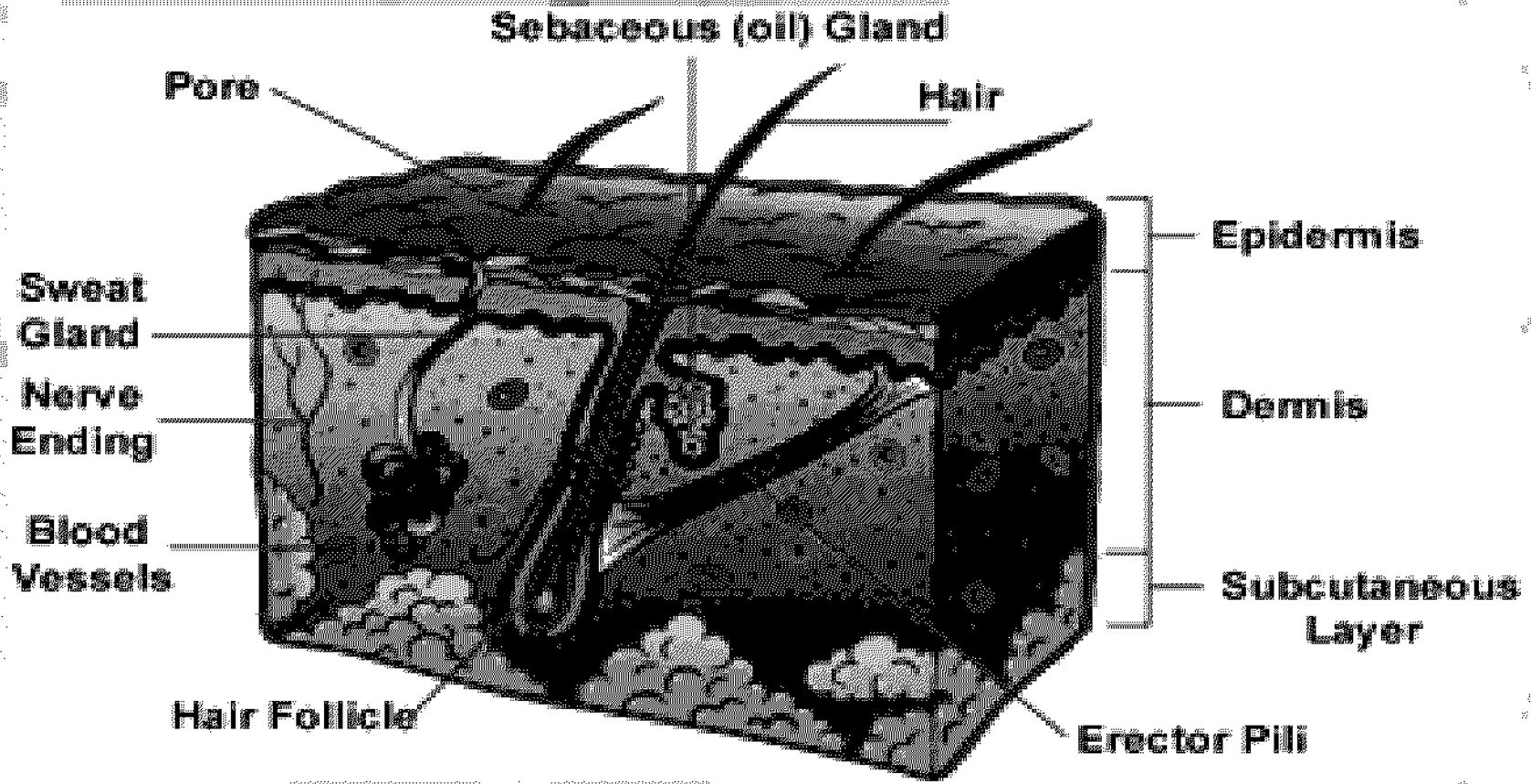
Structure of human skin



Transdermal Drug Delivery

- Painless and patient friendly
- Avoid first pass metabolism: lower dose and reduced side-effects
- Controlled release: better control of symptoms, extended dosing intervals and reduced side-effects
- Major limitation: skin permeability – few TDD applications currently available

Skin Penetration Enhancement

- Optimize physicochemical characteristics of the drug and/or formulation
- Chemical penetration enhancers
- Physical penetration enhancers
  - Iontophoresis
  - Electroporation
  - Sonophoresis/phonophoresis
  - Dermaportation

5 Aminolevulinic acid (ALA)

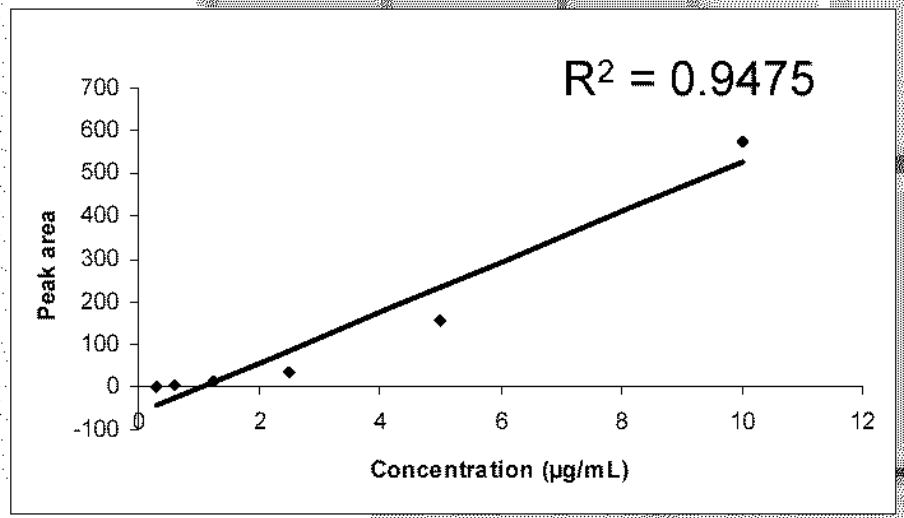
- ALA is a delta amino acid
- It is hydrophilic and zwitterionic at physiological pH
- Used with PDT in the treatment of BCC.
- It is converted into PpIX, precursor of heme
- Exogenous administration of ALA results in PpIX accumulation
- Light activation (PDT) causes destruction of tumours
- Skin permeability of ALA through skin lesions is poor

AIM

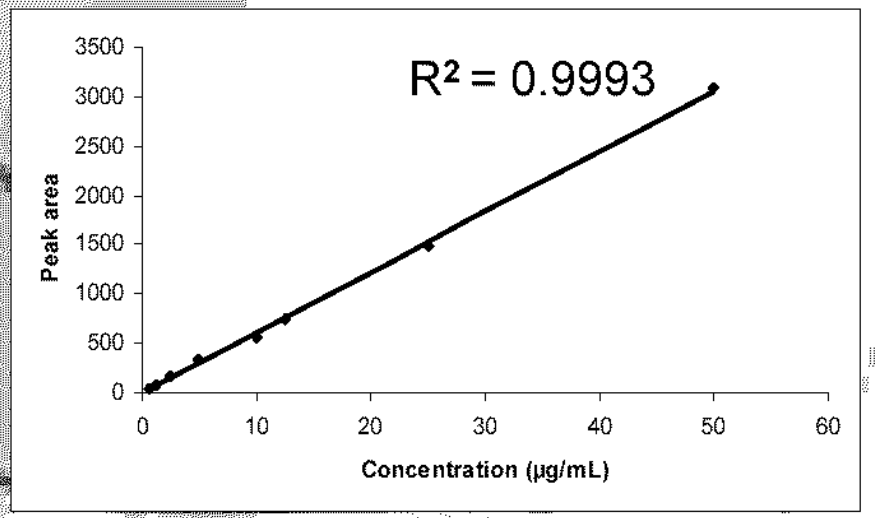
To assess the impact of Dermaportation on the transdermal delivery of ALA

HPLC Method Development

- ALA does not contain a chromophore therefore cannot be detected by UV
- Fluorescence derivitization for developing a HPLC assay.



Standard curve after derivatization at 100^{0}C

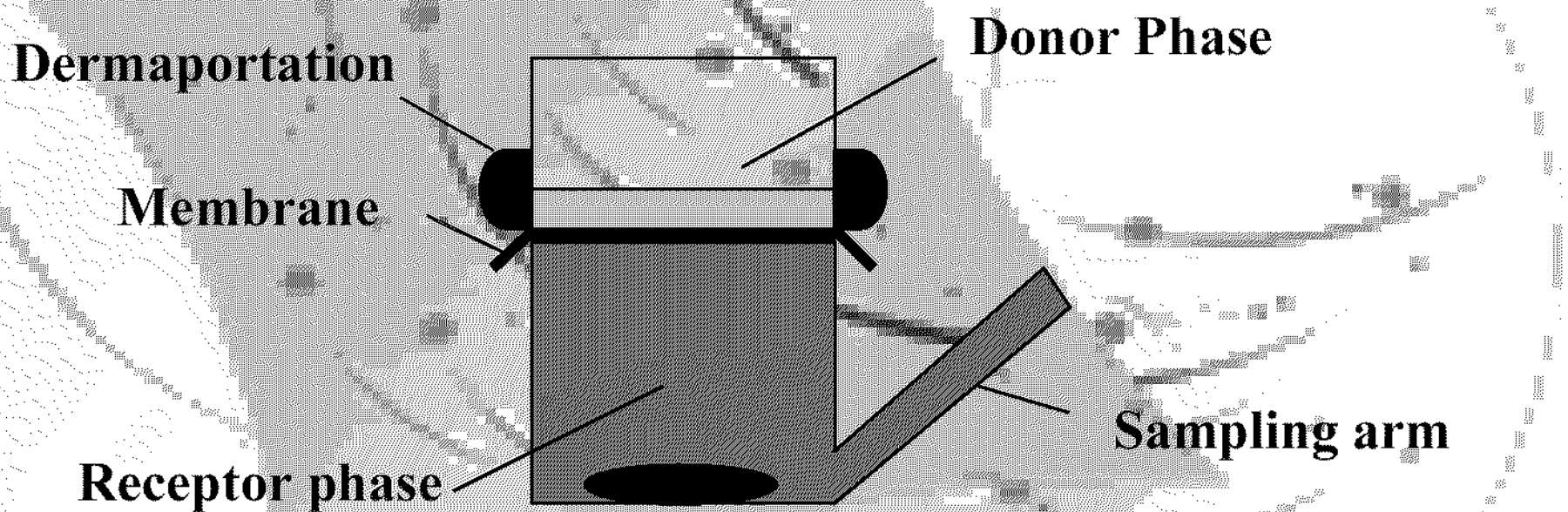


Standard curve after derivatization with Fluorescamine at room temperature

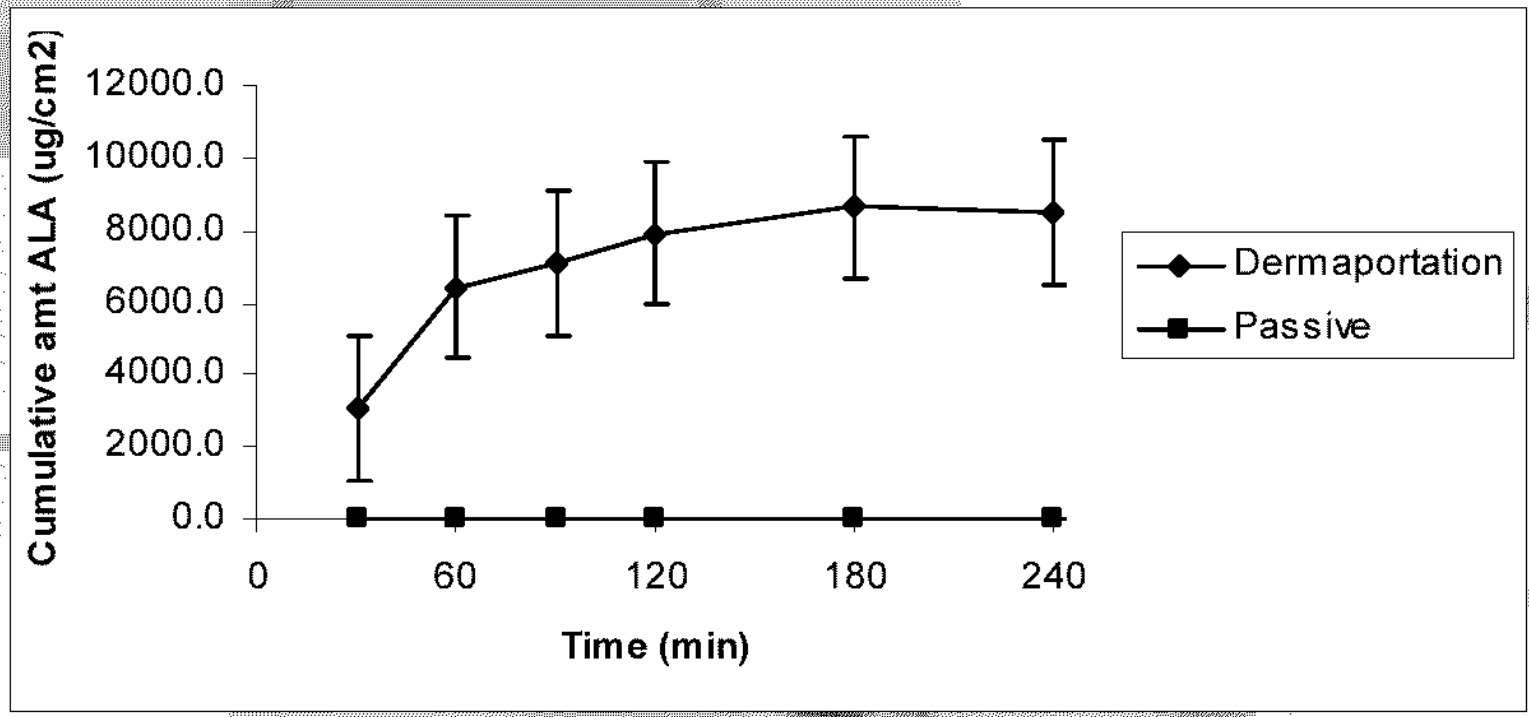
HPLC Assay For ALA Detection

- Amine group of ALA targeted by Fluorescamine
- Linearity $R^2 = 0.9993$
- Limits of detection (LOD) = 120 ng mL^{-1}
- Limit of quantification (LOQ) = 400 ng mL^{-1}
- Accuracy = 99.4%

Dermaportation – *in vitro* diffusion protocol



Dermaportation vs passive diffusion of ALA across human epidermis (mean ± sem)



Dermaportation: ALA flux and Enhancement ratios (ER)

	Flux during Dermaportation ($\mu g.cm^{-2}.h$)	Permeability coefficient ($cm.h^{-1}$)
Passive	0.12	0.006
Dermaportation	76.57	3.82

Conclusions

- The HPLC method developed was accurate and sensitive
- Dermaportation enhanced the transdermal delivery of ALA as compared to passive diffusion
- Dermaportation has potential as a skin penetration enhancement technology – further evaluation with small and large molecules

Curtin University of Technology

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