



APV Focus Group Drug Delivery

Combining Science & Technology to Create Advanced Drug Delivery Systems

INTERNATIONAL ASSOCIATION FOR PHARMACEUTICAL TECHNOLOGY

NEWSLETTER | ISSUE 1/2007

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DRUG DELIVERY EVENTS

Provided by Christoph Blümer

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◇ [Design and Development of Innovative Oral OTC Products \(APV\)](#)

Heidelberg (D), February 14th to 15th 2007

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[2nd European Congress on Life Science Process Technology \(APV\)](#)

Nuremberg (D), March 27th to 29th 2007

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[Drug Delivery 2007](#)

San Francisco (USA), April 9th to 11th, 2007

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[Pharmaceutical Sciences World Congress \(FIP\)](#)

Amsterdam (NL), April 22nd to 25th 2007

[Details](#)

[Workshop on in Vitro-in Vivo Correlation \(IVIVC\) and Biowaivers in Drug Product Development](#)

Heidelberg (D), May 9th to 10th 2007

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[NSTI Nanotech 2007 - Drug Delivery & Therapeutics](#)

Santa Clara (USA), May 20th to 24th 2007

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[Suggest a meeting to be announced!](#)

DRUG DELIVERY PRODUCTS

Provided by Dr. Louise Rosenmayr-Templeton

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Invega™ Extended-Release Tablets (Alza Corp/Janssen L.P.) were approved by the FDA in Dec 2006 for the treatment of schizophrenia. The tablets, which are available on prescription in strengths of 3 mg, 6 mg and 9 mg, have not yet been approved by the EMEA.

Invega™ contains paliperidone, a new atypical anti-psychotic, which is the principle active metabolite of the already marketed, risperidone. The tablets, which are taken once daily, were developed by the Alza Corporation and employ its Oros® Tri-Layer technology.

The Oros® Tri-Layer technology uses osmotic pressure to control the delivery of paliperidone, and consists of a capsule shaped trilayer tablet surrounded by a subcoat and a semi-permeable membrane. The trilayer core consists of two adjacent layers containing drug and excipients, and the "push layer" which contains osmotically active agents but no paliperidone. The semi-permeable membrane allows water to penetrate the tablet but prevents the tablet contents leaving, except via two precision laser-drilled orifices in the dome of the drug-containing end. Each strength is coated with a different coloured water-dispersible overcoat. This overcoat quickly erodes in the aqueous environment of the gastrointestinal tract to reveal the semi-permeable membrane that controls the rate at which water penetrates the tablet core. The hydrophilic polymers of the core hydrate, swell and form a gel on contact with water. This gel containing paliperidone is then pushed by the gradual expansion of the push layer through the orifices, and is released into the GI tract at a controlled rate.

Further details: <http://www.alza.com/> <http://www.invega.com/>

Neupro™ (Schwarz Biosciences GmbH) contains rotigotine, a non-ergoline dopamine receptor agonist, formulated in a transdermal patch. The patches are available in different sizes (10 cm², 20 cm², 30 cm² or 40 cm²) and are designed to release either 2 mg, 4 mg, 6 mg or 8 mg rotigotine over 24 hours. Neupro™ was initially approved by the EMEA in February 2006 as a monotherapy for the early signs and symptoms of idiopathic Parkinson's Disease. However, since then, its approval has been extended to later stages of the disease where it is administered in combination with levodopa. The product is not yet approved in the US. It is also being evaluated for restless legs syndrome, and has been shown to be effective in Phase 3 trials at doses of 2 and 3 mg per 24 hours.

Rotigotine is a drug that undergoes extensive first pass metabolism, is lipophilic at neutral pH and is sensitive to oxidation. Each patch consists of three layers, a non-removable backing layer, a self-adhesive layer containing the drug and other excipients and a protective layer which the patient removes immediately prior to application. The patches are of a matrix design where the drug is present as the free base within a silicone based pressure sensitive adhesive. Each patch contains a drug loading of 0.45 mg/cm², an excess compared to the labelled strength, to maintain a constant thermodynamic activity of the active in the matrix. As rotigotine is sensitive to oxidation, sodium metabisulphite, α -tocopherol and ascorbyl palmitate are included in the formulation.

Further details: <http://www.neupro.de/> <http://www.schwarzpharma.co.uk/>

DRUG DELIVERY COMPANIES (I)

Provided by Gerben Moolhuizen

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NanoDel Technologies GmbH (D-Magdeburg) is a biopharmaceutical company that uses proprietary nanoparticle delivery technology to develop preferentially drugs for the treatment of brain tumors and other diseases of the central nervous system (CNS). NanoDel has developed a patent protected nanoparticle based technology which enables or improves the transport of pharmaceutical active compounds loaded into nanoparticles (NP) across the Blood Brain Barrier.

NanoDel is using its nanoparticle based technology to deliver compounds that are suitable for the treatment of brain tumors and other acute and chronic CNS related disorders, such as brain infections, neuroprotection, epilepsy, Alzheimer's disease and others.

NanoDel's business model is to apply nanotechnology to therapeutically interesting compounds which are either already on the market for other indications but without CNS approval or to revive "sunken drugs" which were not developed for CNS indications due to ADME and side effect related limitations.

Fact sheet

Founded:	2003
Location:	Magdeburg, Germany
Employees:	10
Ownership:	Privately funded Most recent funding round: Dec 2006 / Euro 4 mio
Key technologies:	NanoDel's technology platform consists of combining drugs with polymeric nanoparticles (e.g. polybutylcyanoacrylate). The nanoparticles range in diameter from 50 to 150 nm, and they are dispersed in an aqueous solution. Depending on the method of polymerization, drugs are either attached to the surface and/or are incorporated into polybutylcyanoacrylate-particles (PBCA). The nanoparticles can be stored either in lyophilized form or in solution. The drug-loaded nanoparticle is coated with a surfactant such as polysorbate 80 (= Tween 80). After injection, the surfactant-coated nanoparticles will bind to lipoproteins such as ApoE in the blood and pass the Blood Brain Barrier through a lipoprotein receptor. The technology is applicable to proteins, peptides, plasmids and small molecules.
Product pipeline:	Lead product: nanoparticle/doxorubicin formulation for the treatment of brain tumors. Proof-of-concept in animal models has been established and the product is currently in pre-clinical development. Several other compounds in pre-clinical evaluation.
Website:	http://www.nanodeltech.com
Contact:	Dr. Joachim Bender Chief Executive Officer NanoDel Technologies GmbH Leipziger Str. 44 (Zenit) D-39120 Magdeburg Tel. +49-(0)391-611 7335 Fax +49-(0)391-611 7331 info@nanodeltech.com

ThioMatrix GmbH (A-Innsbruck): The drug delivery technologies are mainly based on thiolated polymeric excipients or designated thiomers. Due to the immobilization of thiol groups on already well-established polymeric excipients such as polyacrylates or chitosans as illustrated in Fig. 1 the following features are strongly improved.

Mucoadhesive properties

As thiolated polymers are capable of forming disulfide bonds with cysteine-rich subdomains of mucus glycoproteins covering mucosal membranes, they provide much stronger mucoadhesive properties than state-of-the-art polymers. These improved mucoadhesive properties of thiolated polymers were meanwhile verified for various polymers. Due to the immobilization of thiol groups the mucoadhesive properties of poly(acrylic acid) and chitosan, for instance, were improved at least 20-fold [M. Marschütz, *Eur. J. Pharm. Sci.*, **15** (2002) 387-394] and 140-fold [A. Bernkop-Schnürch et al., *Int. J. Pharm.*, **260** (2003) 229-237], respectively.

Permeation enhancing effect

The mechanism being responsible for the permeation enhancing effect of thiomers has been discovered to be based on a reversible opening of the tight junctions [A. Clausen et al., *Pharm. Res.*, **19** (2002) 602-608] leading to an up to 10-fold improved uptake of drugs. As the mechanism behind seems to be completely different to that of other permeation enhancers, thiomers can be combined with well-established permeation enhancers such as medium chain fatty acids in order to achieve an additive effect.

In-situ gelling features

Due to the formation of inter- and intrachain disulfide bonds, thioimer gels show pronounced gelling features once getting into contact with oxygen. Nasal delivery systems, for instance, can be administered in liquid form showing thereafter rapid gellation on the nasal mucosa.

Capability to provide a controlled drug release out of polymeric networks

Because of the formation of inter- and intrachain disulfide bonds during the swelling process, the stability of polymeric drug carrier systems is strongly improved. Hence, a controlled drug release for numerous hours up to days is guaranteed.

Enzyme inhibitory properties

Because of their capability to bind Zn^{2+} ions via thiol groups, thiomers are potent inhibitors of most membrane bound and secreted zinc-dependent enzymes.

Efflux pump inhibition

The postulated mechanism of efflux pump inhibition is based on an interaction of thiomers with the channel forming transmembrane domain of efflux pumps such as P-gp and multidrug resistance proteins (MRPs). In thioimer concentrations <0.5%, for instance, a 100% inhibition of intestinal P-gp can be provided [M Werle et al., *J. Control. Release*, **111** (2006) 41-46].

Because of these properties

- the bioavailability of most non-invasively administered class III drugs according to the biopharmaceutical classification system including therapeutic peptides, peptidomimetics and nucleic acids and that of efflux pump substrates can be significantly improved
- the duration of drug action can be significantly prolonged
- a higher efficacy and more accurate dosing of anticancer drugs can be achieved

ThioMatrix's thioimer-technology has been described in extensive peer-reviewed journals [[Click here](#)]. Data about in vivo studies in mice, rats and pigs are available providing strong evidence for the efficacy of this novel drug delivery technology [e.g. A. Bernkop-Schnürch et al. *J. Control. Release*, **106** (2005) 26-33; N. Langoth et al. *Pharm. Res.*, **23** (2006) 573-579]. Moreover, results of clinical trials are open to the public as well [MD Hornof, *J. Control. Release*, **89** (2003) 419-428]. For certain thiomers GMP-material is already available.

The thioimer-technology is worldwide protected by various patents and patent applications. ThioMatrix is open for co-developments utilizing this novel technology.

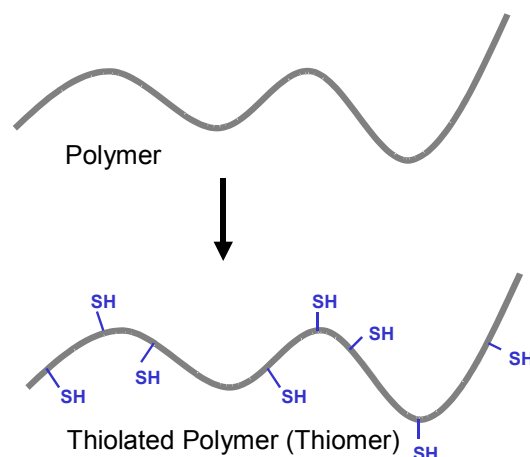


Fig. 1: Schematic presentation of thiomers

Fact sheet

Founded:	2003
Location:	Innsbruck, Austria
Employees:	10
Ownership:	Privately funded
Key technologies:	Thiomer technology
Product pipeline:	Several client products in pre-clinical and clinical testing
Website:	http://www.thiomatrix.com
Contact:	Dr. Birgit Zassler Managing Director Mitterweg 24, A-6020 Innsbruck Tel: +43-(0)512-890046 b.zassler@thiomatrix.com

DRUG DELIVERY TERMINOLOGY

Provided by Dr. Karsten Cremer

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Microparticle

Particle with a diameter of about 1 to 1000 μm . [Write a comment on this definition](#)

"Microparticle" is a rather broad term; it merely defines the approximate size region of a particle. Within the field of drug delivery, it usually refers to solid or semisolid particles. In contrast, the term is not restricted to any particular shape, internal morphology, or composition, except that it is not typically used for aggregated powders (such as granules or pellets) or particles of a relatively pure substance (such as crystals of a drug substance). Well-known examples are microparticles based on biodegradable polymers that are used in many injectable sustained-release products.

German: [Mikropartikel](#)

French: [Microparticule](#)

Spanish: [Provide a translation](#)

[Suggest a term to be defined](#)
[Suggest a definition](#)

Microcapsule

Particle with a diameter of about 1 to 1000 μm having at least one core and one shell region. [Write a comment on this definition](#)

According to the proposed definition, a "microcapsule" is a microparticle having a specific morphology. However, the term is sometimes also used for microparticles which do not have a capsular morphology. This may reflect that, in practice, the difference in morphology between a microcapsule and a matrix-type microparticle may be rather small.

German: [Mikrokapsel](#)

French: [Microcapsule](#)

Spanish: [Provide a translation](#)

Microsphere

Substantially spherical microparticle.

[Write a comment on this definition](#)

Note that the definition only specifies the size range and the overall shape of the particle. While the term itself is not restricted to a specific internal morphology, it is more commonly used for microparticles which do not have a distinct core and shell.

German: [Mikrosphäre \(uncommon in drug delivery terminology\)](#)

French: [Provide a translation](#)

Spanish: [Provide a translation](#)

Provided by Prof. Dr. Karsten Mäder

Stefaan De Smedt (*1967) studied pharmacy at Ghent University and received his M.S. degree in pharmaceutical sciences in 1990. As a scholar of the Belgian Institute for the Encouragement of Scientific Research in Industry and Agriculture, he enrolled in a Ph.D. program at Ghent University, under the direction of Prof. J. Demeester followed by a study rheology at the Catholic University of Leuven. He received the Scott Blair Biorheology Award in 1993-1995 for his work on the structural characterization of hyaluronan solutions. To study diffusion phenomena in polymer solutions, he collaborated with Prof. Y. Engelborghs at the Laboratory of Biomolecular Dynamics of the Catholic University of Leuven.



In 1995, he joined the pharmaceutical development group of Janssen Research Foundation. Since 1997 he has been a post-doctoral fellow of F.W.O.-Vlaanderen at the Laboratory of General Biochemistry & Physical Pharmacy of Ghent University and at the Department of Pharmaceutics of the University of Utrecht. In October 1999 he became Professor in Physical Pharmacy & Biopharmacy at Ghent University.

Since 2004 Professor De Smedt has been Assistant Editor for Europe of the Journal of Controlled Release. He is a representative of the members of Eufeps (European Federation for Pharmaceutical Sciences) in the Eufeps Council and takes the chair for the Eufeps Committee for Training and Education. Professor De Smedt is a member of the Belgian and Dutch Society for Pharmaceutical Sciences, Controlled Release Society, the Biophysical Society, the American Association of Pharmaceutical Scientists and the European Society for Gene Therapy. He is one of the scientific founders of Memobead Technologies, a spin-off from Ghent University focussed on the development of encoded microcarriers for drug screening and diagnostics. He is winner of the "Young Investigator Achievement Award 2006", awarded by the Controlled Release Society. Stefaan De Smedt is author and co-author of over 75 publications.

FEATURED ARTICLE

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CURRENT TTS AND THE BIOLOGICAL INTERFACE

by Dr. Michael Horstmann, [LTS Lohmann Therapie-Systeme AG](#), Lohmannstraße 2, D-56626 Andernach

INTRODUCTION

During the last 25 years, an increasing number of transdermal therapeutic systems have been registered in the EU, US and Japan.

TTS (Transdermal Therapeutic Systems) deliver their active ingredient load via a adhesive polymer interface systemically to human blood circulation and ultimately the target organ. Nitroglycerin, Scopolamine, Clonidine, Nicotine, Estradiol, Levonorgestrel, Norethindrone Acetate, Norelgestromine, Ethinyl Estradiol, Tulobuterol, Fentanyl, Buprenorphine, Selegiline, Rotigotine, Testosterone, Isosorbide Dinitrate and Oxybutynin are APIs with current importance for clearly systemic indications. Some of the active ingredients like Estrogens and Progestogens are typically combined to synergistically treat perimenopausal disorders or providing contraception. Other indications include cardiovascular protection (blood pressure, coronary perfusion), smoking cessation, asthma, pain, depression, Parkinson's disease, steroid hormone substitution and control of the urinary bladder.

Early devices have been predominantly membrane-controlled reservoir systems, quite often liquid-filled. Nowadays, most TTS do not contain a specifically localized, foil-like controlling membrane. But if they do, the mechanical behaviour of such systems is not tangably different to transdermal matrix devices. This is accomplished by using soft polymeric reservoirs and by reducing the overall thickness of such new generation membrane systems. We observe now a larger variety of constructions applying new ideas of modification of thermodynamic control, like the addition of droplet-like inner phases, but also use of low diffusion polymers like SIS (styrene-isoprene-styrene-)copolymers. The new release mechanisms appear to differ more within each other than compared to the two "classical" concepts of membrane versus matrix design.

Commonly, all transdermal systems share the therapeutic advantage of enabling a controlled delivery over 1,3,4 or even 7 days with a single patch. Quite often, bypassing the first-pass-effect, the dose utilization is much enhanced compared to oral and side effects are reduced by avoiding blood level peaks. All systems share as well their nature in forming a transient adhesive joint between the skin and the system (compare figure). The selection of suitable pressure-sensitive adhesives is important for the therapeutic (and economic) success of modern systems.

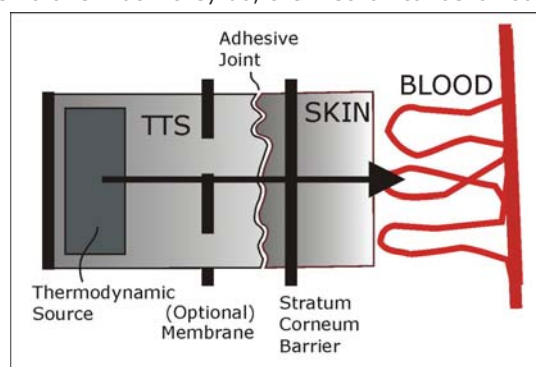


Fig. 1

But doctors and even regulatory authorities are often unaware of the biological contributions of individual skin on the reliability of this adhesive joint. Inappropriate adhesion (be it failure to adhere, too strong initial adhesion, too early detachment, problems with sweating...) is quite often mistakenly attributed to assumed deviations in manufacturing or inadequate polymer specifications.

In a similar way, comparatively high variability of the drug flux is expected from transdermal systems and, if recorded, is merely attributed to pharmaceutical patch properties. In this parameter, however, pharmacokinetic studies quite often confirm sufficiently low variation of blood levels with regards to Cmax, AOC or DOF.

Both aspects, skin adhesion and delivery performance, share the necessity of considering the interaction between the biological absorption organ, the stratum corneum of the skin and the pharmaceutical system ("patch").

Insofar, it is no surprise that both pharmaceutical industry and (increasingly) regulatory scientists are not happy with current, purely kinetic, test methods for in-vitro release on one side and in-vitro testing of adhesion just on artificial metal surfaces. This article shortly summarizes some of the recent trends in this area and invites for further reading and discussion.

POLYMERS

Since the early times of transdermal delivery, three main adhesive systems have been used:

1) Polyisobutylene (PIB)-based adhesives:

Polyisobutylene is a family of lipophilic polymers which are available from low-molecular liquids to high-shear non adhesive solids. Their advantage is comparatively high adhesion to human skin, easiness of modification by mixing different molecular weights or adding petrolatum or related polymers like Polybutene.

Active Ingredient(s)	Brand (e.g.)	Polyacrylic	Silicone adhesive	Polyisobutylene	Polybutene	PVP	Poly(isopren-co-styrol)	Colophony (derivative)
Nitroglycerin	MinitranS®	x						
Nitroglycerin	Nitroderm TTS®		x					
Nitroglycerin	deponit® NT	x						
Nicotine	NICORETTE®			x	x			
Nicotine	Nicotinell®	x						
Nicotine	NiQuitin®			x	x			
Estradiol	Estraderm TTS®			x				
Estradiol	Cutanum®	x						
Estradiol	Dermestril®-Septem	x						
Estradiol	Estramon®	x						
Estradiol	Estradot®	x	x			x		
Estradiol	Fem7®						x	x
Estr.+Levonorgestrel	Fem7® Combi						x	x
Estr.+Norethindronacetate	Estragest TTS®			x				
Estr.+Norethindronacetate	Estalis® sequi	x	x			x		
E.-estr.+ Norelgestromin	EVRA®			x	x	x		
Fentanyl	Durogesic® SMAT	x						
Fentanyl	Fentanyl-HEXAL® TTS		x					
Fentanyl	Fentanyl-HEXAL® MAT	x						x
Fentanyl	Fentanyl-ratiopharm®	x						
Fentanyl	Matrifen®	x						
Buprenorphin	Transtec® PRO	x				x		
Rotigotin	Neupro®		x			x		
Oxybutynin	KenteraTM	x						

2) Polyacrylates

Polyacrylates are polymers of acrylic acid esters of mostly lipophilic functional groups before polymerisation. Besides those acrylic ester monomers (and acrylic acid itself as a minor component), also vinyl acetate is used.

In the sequence of decreasing frequency (not necessarily the typically added proportion), 2-ethylhexylacrylate, vinyl

acetate, 2-3 epoxypropylmethacrylate, 2-hydroxyethyl acrylate, isooctylacrylate, acrylic acid, acrylamide, butyl acrylate, methyl acrylate, 1-vinyl-2-pyrrolidone and hexane-1,6-diyl-bis-methacrylate are common monomeric raw materials. These are polymerized to form the commercially available coatable solution. One advantage of acrylic adhesives is besides improved skin compatibility to allow tailor-made adjustment of adhesion, tack and cohesion. Polarity is adjustable, much dependent on the selected comonomers. Generally, solubility and permeability are higher than in PIBs.

3) Silicone pressure sensitive adhesives

Silicone pressure-sensitive adhesives are generally condensation products of polydimethyl (or polydimethyldiphenyl) siloxane ("polymer" component) with a resin-like three-dimensional silicate structures end capped to a large extent with trimethylsiloxy groups ("resin"). The higher the resin content, the lower the tack, and cohesive strength is improved.

Silicone adhesives are considered physiologically safe and well documented but expensive. Their adhesive behavior is soft and gentle but may not reach the strong bonding effect of rubber-based adhesives. Most silicone polymers may be reapplied to skin without major loss of tack, which is interpreted in terms of their apparent absence of a stripping effect. Because of their low solubility but high diffusivity for most active ingredients and their inertness, silicones provide a unique part of the toolbox of transdermal adhesives.

4) Other systems

Other polymer systems may be suitable but increasing regulatory demands on safety and documentation provide a major hurdle to apply recent progresses of polymer synthesis to pharmaceuticals.

For historical and cultural reasons in Japan, water-based cataplast-type patches are much more popular there than in Europe and US. Water-based common gel-formers like cellulose derivatives but also PVP may be used as a backbone for such formulations. These are however currently only marketed in topical patches in some EU-countries and US.

The presence of PVP in some of the products distributed in Europe is quite often based on its potential to modify the release

SIS copolymer (styrene-isoprene styrene-copolymer) is a very cohesive backbone and requires high amounts of resin addition. Modern resins which are refined and hydrogenated derivatives of colophony are in use to modify adhesion both of PIB as well as polyacrylic adhesives.

ADHESION

The general term "adhesion" can be split into four different distinguished properties/tests of transdermal therapeutic system layers:

1) Peel adhesion test on artificial steel/metal surface

This property (and test) reveals the ability of the polymer surface to be forming a force-resistant surface-based joint to an artificial test surface like steel or aluminum. This test already lacks predictiveness. It is however the most commonly filed test for quality control and is sufficiently sensitive for batch-to-batch variation.

2) Shear force (viscosity)

The cohesiveness of a polymer / polymer formulation is critical for preventing from patches to stick into the inner side of sealed pouches or to form residue rings on the skin after wearing. Specific tests for this property are available but play a role only as a research tool. For formal quality tests, the results of improper cohesion are more easily visible with the appearance of pouched patches.

3) Tack

Tack and tests to measure tack (rolling ball tack, probe tack,...) refer to very immediate properties of adhesiveness of patches. This ability to form spontaneous formation of joints is normally not necessary or preferred in transdermals as it makes repositioning of systems more difficult.

4) Peel Adhesion of Release Liner

All marketed transdermal patches are supplied with a protective liner that is detached immediately before use. It is obvious that the release force of this liner has to remain within manually practical limits for the shelf life of products and a peel test is a quite common and well-accepted specification criterion. In a kind of recent trend, some regulatory scientists (Wokovich et al. 2006) call for extending the physical in-vitro-tests. The lack of in-vivo/in-vitro correlation is accepted, but the reason is attributed to physical surface phenomena like differences in surface energy instead of realising that shortly after applying a patch, the real remaining bonding effect is between biological stratum corneum layers and no longer a detachment between "clean" polymeric surfaces. It is insofar not surprising that not much observation is made upon the recorded adhesion properties in clinical / bioequivalence studies. And if, they are often misinterpreted e.g. as the result of inhomogeneous polymeric coating. Again (taken from Horstmann et. al., redrawn), the figure shows the

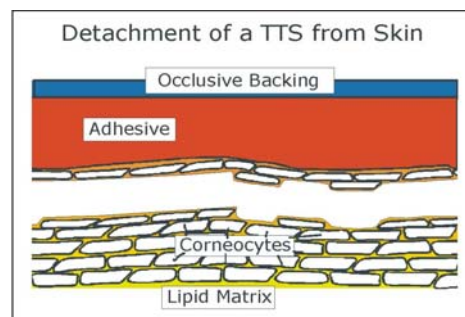


Fig. 2

remarkable difference between human individuals in their adhesive detachment force even when a set of three different formulae with varying in-vitro adhesion is used:

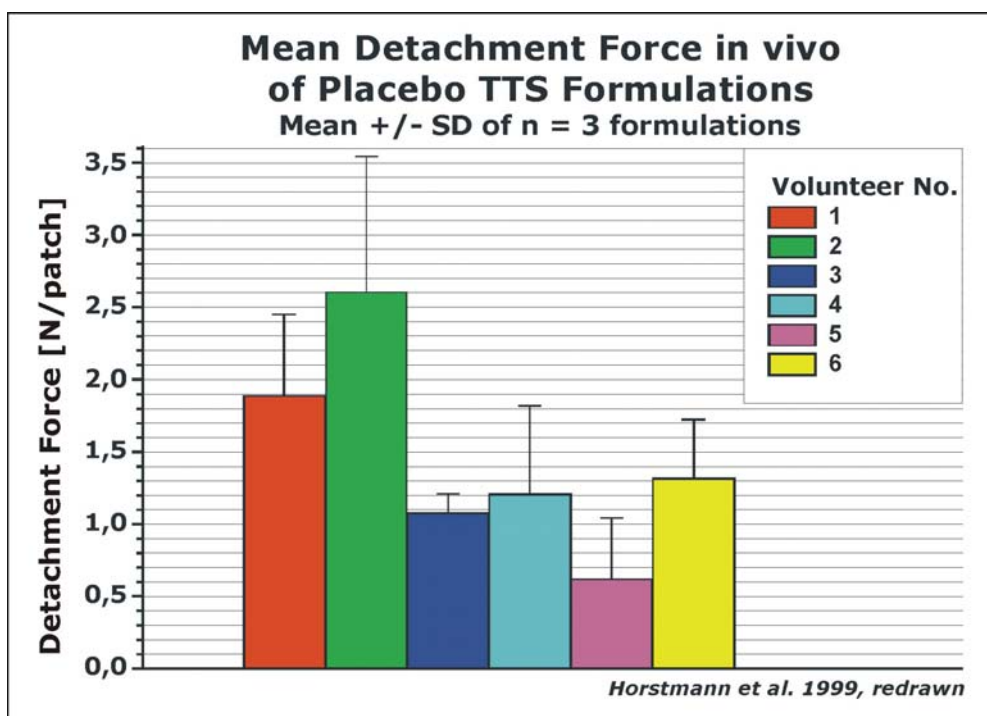


Fig. 3

As a matter of fact, for each formula, good and bad "adherers" can be identified and in few individuals, patch application is not possible at all, due to non-adhesion or overly high initial adhesion. Such patients may switch to another recipe or to tablets.

CONCLUSION

Modern transdermal systems still make use of the three basic polymeric concepts to a comparable extent, due to different drug delivery concepts and also adhesive property requirements. The test of choice to confirm the ability of TTS to adhere is to embed careful adhesiveness observation into pivotal clinical trial concepts. As a quality control link from market batches back to biobatches, peel adhesion is considered to be sensitive and sufficient in usual cases.

FURTHER READING

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The APV Drug Delivery Focus Group (APV DD) is a section of the APV (Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V. / International Association for Pharmaceutical Technology), a major European society for those sharing a professional interest in pharmaceutical sciences. The Focus Group was established in 2003 in response to the increasing importance of drug delivery within modern pharmaceuticals. [Read more...](#) [Contact us...](#)

COMBINING SCIENCE AND TECHNOLOGY TO CREATE ADVANCED DRUG DELIVERY SYSTEMS

OUR MISSION STATEMENT:

Modern drug delivery research and development is a truly multidisciplinary approach and must combine all relevant scientific, technical, medical and regulatory aspects required for the design, preparation, testing, manufacturing and registration of drug delivery systems and their components. It is the mission of the APV Drug Delivery Working Group to foster and promote all aspects of research and development required to transform drug molecules into safe, applicable and acceptable drug delivery systems, which provide therapeutic benefit, convenience to the patient and improve patient compliance.

Our mission includes in particular the following tasks:

- Thoroughly understanding the physical-chemical and biopharmaceutical properties of the drug substance to be delivered and the components of the drug delivery system
- Understanding the biological barriers and the interactions of the drug molecule and its delivery system with the biological environment and the biological target including PK/PD and PK/safety relationships
- Research on excipients, materials and technologies required for the design, preparation and manufacturing of drug delivery systems for a selected route of administration
- Development and understanding of methods for in vitro and in vivo evaluation of drug delivery systems and their components
- Knowledge of regulatory requirements for clinical testing, manufacturing and registration of drug delivery systems

All disciplines relevant to the above mentioned areas of drug delivery R&D are invited to contribute to the APV Drug Delivery Group:

Pharmaceutics, Biopharmaceutics, Analytics, Biology, Physical Chemistry, Biochemistry, Physics, Engineering Sciences, Nano Technology, Material Sciences, Polymer Science, Toxicology, Drug Safety, Clinical Research, Drug Regulatory Affairs, etc. [Read more...](#)

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