

8. TRANSDERMAL DRUG DELIVERY GLOSSARY

Adhesion - The physical and/or chemical bond that develops between two materials when they are contacted.

Adhesive Anchorage - Ability of substrate to adhere to adhesive or adhesive-containing formulation.

Aluminum Vapor Coat - Thin coating of aluminum applied to a film to enhance barrier properties.

Appearance - Outward aspect of film such as clear, translucent, or colored.

Application - Intended use of material such as backing, membrane, or liner.

Backing - The material, i.e. film, foam, nonwoven, etc., used as the outermost layer of the transdermal or medical system to protect the product during the wear period.

Barrier - Term applied to substrate (e.g., backing, membrane) referring to substrates' ability to block diffusion of specific materials such as excipients, drugs, water vapor, etc.

Bioavailability – The amount of drug that is available to exert a pharmacological action.

Breathable - A material with breathable qualities allowing moisture and/or oxygen to readily diffuse through.

Caliper - Measure of the thickness of film in mils. One mil is equivalent to 0.001 inch.

Carrier - A liner-like material onto which a second material is laid prior to wind up because the second material is not capable of forming a usable roll without the support material.

Commercial Use - Indication as to whether material is currently used in commercial product.

Conformability - Ability of material to expand and contract with applied force.

Component (Transdermal) - See Transdermal Component.

Corona Treatment - Application of electrical charge to surface of films to enhance adhesion and printability.

Drug-in-Adhesive (DIA) – A system in which the drug is incorporated directly into the adhesive, rather than as a separate layer. This system is used for smaller molecular compounds which are among the easiest compounds to deliver via transdermal means.

Drug Master File (DMF) - Submission to the Food and Drug Administration (FDA) used to provide confidential, detailed information about the manufacturing of transdermal components. This includes the manufacturing facilities, processes and materials. Note: DMFs for 3M components can be referenced in applications to the FDA.

Excipient Resistance - Resistance of film to the uptake and/or transmission of enhancers, excipients, drugs, or other chemicals.

Excipient - Ingredients contained within a drug product that are considered to be inactive from a pharmacological perspective. Typical categories include: solubilizers, stabilizers, permeation enhancers, fillers, binders, etc.

Elongation - The percent increase of length in a given direction that occurs at the fracture point of a material under applied force.

Estrogen Replacement Therapy - Regimen to restore circulating levels of estrogen to average pre-menopausal levels in women, to relieve menopausal symptoms and reduce the risk of osteoporosis and cardiovascular disease.

EVA - Ethylene Vinyl Acetate. Copolymer of ethylene and vinyl acetate, typically used for membranes or backing films. EVA films are flexible, printable and heat-sealable, with high oxygen transmission rates. These films can be laminated directly to adhesives.

Film - An unsupported, typically organic, non-fibrous, thin, flexible material of a thickness not exceeding 0.010 inch.

First-Pass Effect – Drugs that are ingested orally must pass through the liver, where they undergo metabolism before entering the bloodstream. This ‘effect’ often results in a reduced amount of active drug available to reach the site of action and means that drugs may have to be given in higher doses to compensate. Drugs administered via the skin, inhalation or injection are not subject to first-pass effect, and therefore may be administered in lower doses.

Fluoropolymer - The polymeric coating material that imparts the release characteristics to 3M transdermal release liners.

Foam Tape - Adhesive-coated polyolefin foam with the adhesive protected by a liner.

Heat Sealable - Material that is capable of being bonded to itself or to another substrate using heat.

High Release Liner – See Liner. A release liner that can be removed with moderate force from the material to which it is adhered. A liner with a higher release may be desired based on the consistency of the adhesive matrix or to aid in patch application to the skin.

Laminate - Two or more materials combined in layers to form a single substrate.

Liner - The film, removed and discarded prior to patch application, that protects the transdermal system by covering the adhesive side.

Low Release Liner – See Liner. A release liner that can be removed with little force from the material to which it is adhered. A liner with a lower release may be desired because of the shape of the patch or to make it easier for the person applying the patch to separate the liner from the patch.

Matrix System - Skin-controlled transdermal system with no membrane, which incorporates a drug-in-matrix layer between release liner and backing layers. In general, this type of system relies on characteristics of the skin to control the rate at which the drug diffuses into the body.

Melt Blown - A process for producing fibrous webs or articles directly from polymers or resins, using high-velocity air or another appropriate force to attenuate the filaments. The differences between melt-blown nonwoven fabrics and other nonwoven fabrics, such as degree of softness, cover or opacity, and porosity can generally be traced to differences in filament size.

Membrane - A material placed between the drug formulation and the final layer of adhesive. The membrane may be sealed to the backing to form a pocket to enclose the drug-containing matrix or used as a single layer in the patch construction. The diffusion properties of the membrane are used to control availability of the drug and/or excipients to the skin.

Moisture Vapor Transmission Rate (MVTR) - Measure of the ability of film to transmit moisture vapor or water.

Multi-layer Drug-in-Adhesive System - Transdermal system, which tailors the rate of delivery of a drug via the use of layers of drug, membranes and adhesives. This type of system is particularly useful when prolonged drug delivery is desired.

Non-Occlusive – Refers to a material's ability to allow diffusion. Generally used in characterization of backings with respect to moisture vapor and oxygen diffusion. A non-occlusive backing allows a higher diffusion rate for moisture vapor and oxygen.

Nonwoven - A fabric consisting of an assembly of textile fibers (oriented in one direction or in a random manner) held together by mechanical interlocking or fusing of thermoplastic fibers.

Occlusive - Refers to a material's ability to limit diffusion. Generally used in characterization of backings with respect to moisture vapor and oxygen diffusion. An occlusive backing would have very low diffusion rates.

Overlay - An adhesive-coated component placed as protection over a cream, ointment or transdermal patch that has been applied onto the skin. Overlays are generally film, foam or nonwoven material, adhesive-coated or taped to the skin.

Oxygen Transmission - Measure of the ability of film to transmit oxygen (O_2).

Polyethylene (PE) - Widely used transdermal backing. A polymer of ethylene, $CH_2=CH_2$, having the formula $(-CH_2-CH_2-)_n$, which is produced at high pressures and temperatures in the presence of any one of several catalysts, depending on the desired properties for the finished product. Polyethylene is resistant to water, acids, alkalis, and most solvents.

Polyester (Polyethylene Terephthalate) - A film produced from the condensation reaction between ethylene glycol and terephthalic acid. The film is strong, has good chemical resistance, typically contains no plasticizers and has good transparency. Polyester is often combined with a more pliable film to form a backing or functions as a substrate or base material for release liners for transdermal systems.

Polyolefin - Group of plastics that are polymers of various alkenes or olefins. The most widely-used in transdermal systems are polyethylene and polypropylene.

Polypropylene (PP) - Plastic polymer of propylene, which resists moisture, oils, and solvents.

Polyurethane (PU) - Generally, a polymer connected by urethane groups. Polyurethane film is heat sealable and printable, with high MVTR and O₂ transmission, and good resistance to oils and grease. Polyurethane is affected by acids, alkalies, solvents, ketones and alcohols.

Printability - Ability of film to accept and retain print for product identification or other intended purposes.

Release - The measurement of force needed to separate two materials which have been bonded together. Generally refers to force required to remove of protective liner from adhesive.

Reservoir - A transdermal system that contains a rate-controlling membrane, with the drug in a reservoir. In general, this type of system is used when the delivery compound is of higher molecular weight and therefore more difficult to deliver transdermally.

Safety Profile - Safety information for a material, including Cytotoxicity, Primary Skin Irritation, and USP Class V Testing for Plastics, Irritation, Sensitization.

Single-layer Drug-in-Adhesive System - Type of drug-in-adhesive system characterized by the inclusion of the drug directly within the skin-contacting adhesive.

Surface Finish - Texture of film such as rough, smooth, or matte.

System (Transdermal) – See Transdermal Drug Delivery System.

Tensile Strength - The greatest force pulling in the lengthwise direction that a given material can bear before tearing. Measured in weight per sample width (e.g. lbs/in width or gms/25 mm width).

Transdermal – Delivery of a substance through the skin.

Transdermal Component - Non-drug materials that are used in transdermal systems, such as backings, membranes and liners.

Transdermal Drug Delivery System - A drug delivery system that involves the application of a drug to the skin to achieve therapeutic effects.

Ultra-Barrier - Refers to a material that provides maximum occlusivity, allowing almost no moisture or oxygen to diffuse through.