



Do transdermal patches really last for 24 hours as stated in their product claims?

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Summary

The legalization and use of medical cannabis and cannabidiol (CBD) as a medicine have been a point of focus for medical professionals and policymakers across the world. The United Nations commission voted on December 2, 2020 to remove cannabis from a category of the world's most dangerous drugs. The decision could clear the way for an expansion of medical cannabis research for medical purposes.

The Commission for Narcotic Drugs, based in Vienna and includes 53 member states, considered a series of recommendations from the World Health Organization and voted on reclassifying cannabis and its derivatives. The attention centered on a key recommendation to remove cannabis from Schedule IV of the 1961 Single Convention on Narcotic Drugs — where it was listed alongside dangerous and highly addictive opioids like heroin.

Many countries look to global conventions for guidance. The United Nations recognition is a symbolic win for advocates of drug policy change who say that the international law is out of date. There is a growing interest by patients who are seeking effective management of their medical conditions without the discomfort of the known side effects and dangers with conventionally prescribed pharmaceutical therapies.

The purpose of this abstract is to explore the absorption of transdermal patches that contain cannabinoid medicines administered through a transdermal application for a 24-hour duration. This evidence is derived from an independent absorption study by Teledyne Hanson Research, Analytical Research Center, 700 Chestnut Ridge Road, Chestnut Ridge, NY 10977.



Introduction

Transdermal drug delivery has made an essential contribution to medical practice. First-generation transdermal delivery systems have continued their steady increase in clinical use for delivery of small, lipophilic, low-dose drugs. Transdermal delivery also provides steady and consistent permeation of a drug through the skin. This leads to more constant drug levels in plasma, which is usually the goal of therapy. The lack of peaks and troughs in plasma concentration can reduce the risk of side effects.

As time has progressed, a second-generation delivery system using chemical enhancers, non-cavitational ultrasound, and iontophoresis have also resulted in clinical products; the ability of iontophoresis to control delivery rates in real-time provides added functionality.

A third-generation delivery system target their effects on the skin's barrier layer of stratum corneum using microneedles, thermal ablation, microdermabrasion, electroporation, and cavitational ultrasound. Microneedles and thermal ablation are currently progressing through clinical trials for delivery of macromolecules and vaccines, such as insulin, parathyroid hormone and influenza vaccine.

A fourth-generation delivery system utilizes medical cannabis and cannabidiol in a transdermal patch. As patients are challenging their medical providers to provide additional treatment options for their illnesses, they are inclined to explore the utilization of medical cannabis or cannabidiol.

Analysis:

Teledyne Hanson Research was hired to perform independent diffusion tests of various CBD patch samples.

Twelve patches containing different label claim amounts of cannabidiol as listed below were submitted for blinded testing to Teledyne Hanson Research for diffusion rate determination through a membrane using a vertical diffusion cell system. The test was performed using available equipment at THR's laboratory.



Sample information: Transdermal patches of various brands as listed below.

Sample #	Sample ID	Label Claim mg/patch	ARC Sample ID
1	Nano CBD +	20	1020-033
2	Panacea Pain Relief	20	1020-034
3	Trokie Triple strength	25	1020-035
4	Mary's Nutritional	10	1020-036
5	Pure Ratios Hemp Extract	40	1020-037
6	Uncle Buds fast acting	35	1020-038
7	Pure Kana infused CBD	60	1020-039
8	The Good Patch	20	1020-040
9	Select CBD	60	1020-041
10	Manna Patch	40	1020-042
11	CBD Living Patch	50	1020-043
12	Spectral Analytics	50	1020-044

- Reference:**
1. USP 42, NF 37
 2. USP <621>, Chromatography
 3. USP <724>, Drug Release
 4. USP <1724>, Semi-Solid Drug Products – Performance Tests

**Materials and Reagents:**

Material/Reagent	Manufacturer, Lot No. and Expiration Date
Ethanol, HPLC	Millipore, Lot# 59077949, Exp: 03/23
Acetonitrile, HPLC	VWR, Lot# 0000246794, Exp: 10/23
Ammonium Acetate, HPLC	Acros Organics, Lot# A0397842, Exp:23 Jul 2023
Acetic Acid, ACS	Lot# 58264, Exp: 06 Jan 2022
PES Membrane	Pall, Lot# 35696534
Purified Water, USP	In House - ELGA DI Water System

Reference Standards:

Reference Standard	Manufacturer, Lot No. and Expiration Date
Cannabidiol Standard	Restek, Lot# A0153779, Exp: Oct 2021

Diffusion Test Parameters:

Parameter	Condition
Instrument Name	Phoenix RDS, ID: DC-030, Cal Due date: January 2021
Cell Size	Medium cell with 30mm mixer, 15mm orifice, 4mm depth
Receptor solution	Ethanol 50 % v/v with water
Cell Temperature	32.0°C \pm 0.5°C
Stirrer Speed	600 RPM
Membrane	PES Membrane, 0.45 μ m, 25mm
Time Points (hrs.)	12 and 24
Sample Volume	400 μ L
Wash Solution	1:1 Ethanol: Purified Water

**HPLC Test Parameters:**

Parameter	Condition
Instrument Name	Shimadzu HPLC, ID: LC-017, Cal Due date: Feb 2021
Data collection Time	10 minutes
Injection Volume	25 μ L
Mobile Phase	3:1 Acetonitrile: Ammonium Acetate Buffer, vacuum filtered and degassed solution
Flow Rate	1.0 mL/min
Detection Wavelength (λ)	220nm
Column Temperature	35.0° C \pm 1.0 °C
HPLC Column	Ascentis C18 10cm x 4.6mm, 3 μ m, SN 176227-03

**Results:**

The results obtained using the test parameters shown above are presented in the tables and graphs below. The release rates, in mcg/cm² is shown in Result Table 1. Single time point of 24-hour samples were tested so graphical presentation of release rate is not appropriate for this study.

Sample #	Sample ID	Label Claim mg/patch	Amount released mcg/cm2
1	nano CBD + \$7.00	20	17.5
2	Panacea Pain Relief \$7.50	20	1747.6
3	Trokie Triple strength \$9.50	25	187.2
4	Mary's Nutritional \$7.00	10	181.9
5	Pure Ratios Hemp Extract \$18.00	40	4242.3
6	Uncle Buds fast acting \$16.99	35	140.2
7	Pure Kana infused \$17.99	60	4373.7
8	The Good Patch \$12.00	20	1626.7
9	Select CBD \$9.99	60	1674.4
10	Manna Patch \$19.00	40	1311.6
11	CBD Living Patch \$15.00	50	2247.5
12	Spectral Analytics Inc. \$13.00	50	1842



Conclusion:

The amount released from the individual products during the diffusion study is presented above. Various factors such as product formulation, size, shape, adhesive, substrate, and backing material with the combination of binding characteristics and solubility of cannabidiol in the receptor solution influenced the results. All patch samples were tested in an identical environment.

Sample numbers Samples 5 (Pure Ratios Hemp Extract), 7 (Pure Kana infused), 11 (CBD Living Patch), and 12 (Spectral Analytics) display significantly higher released amounts due to the cut made on samples to size them to fit on the diffusion cell cap orifice. Samples 5 (Pure Ratios Hemp Extract), 7 (Pure Kana infused), 11 (CBD Living Patch), and 12 (Spectral Analytics) utilizes a different API delivery system than the other samples, namely a reservoir to hold the cannabidiol oil directly prior to application.

As established in this independent laboratory study, it has proven that the Spectral Analytics Inc.'s transdermal patch is effective for a 24-hour time period with a consistent release which is far superior with many of the other transdermal patches within the industry.

An advantage of a transdermal drug delivery route over other types of medication delivery such as oral, topical, intravenous, intramuscular, etc. is that the patch provides a controlled release of the medication into the patient, usually through either a porous membrane covering a reservoir of medication or through body heat melting thin layers of medication embedded in the adhesive. If patients are using an effective transdermal patch as demonstrated in this laboratory study, they can rely on receiving cannabinoids for a 24-hour time period.