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(54) **ELECTROKINETIC DRUG DELIVERY APPARATUS**

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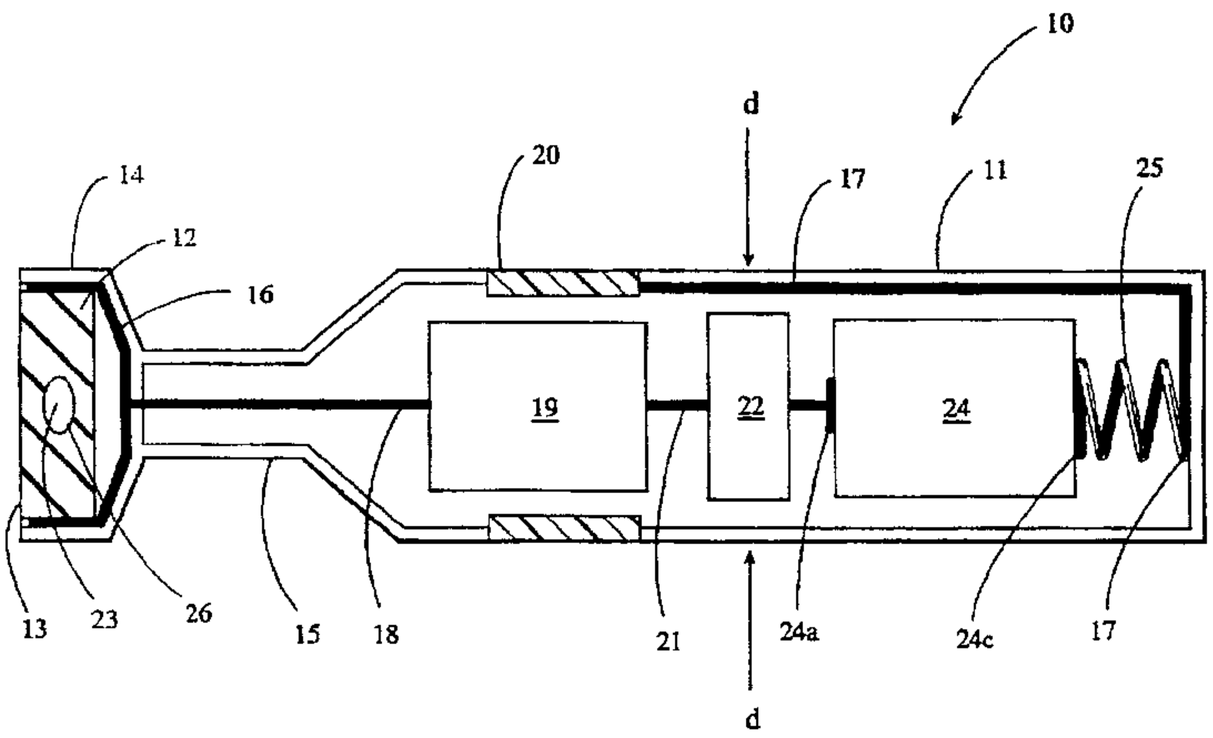
(57) **ABSTRACT**

A portable iontophoresis apparatus for facilitating delivery of medication across the cutaneous membrane into adjacent underlying tissues and blood vessels. The apparatus employs a modular, detachable non-reusable medicament-containing applicator electrode which is adapted to attach to a base assembly. The apparatus is designed to be hand-held and includes a circumferential tactile electrode band on the base assembly which provides electrical connection between the skin of the user's hand and one pole of a bipolar power source housed within the base assembly. The opposing pole of the power source is connected to the applicator electrode. The user's body completes the electrical circuit between the applicator and tactile electrodes. A method for using the device for the treatment of Herpes simplex infection and related viral infections which produce similar cutaneous lesions is presented. The apparatus, when used in accordance with the method described herein, demonstrated >90% treatment efficacy in clinical trials.

24 Claims, 1 Drawing Sheet



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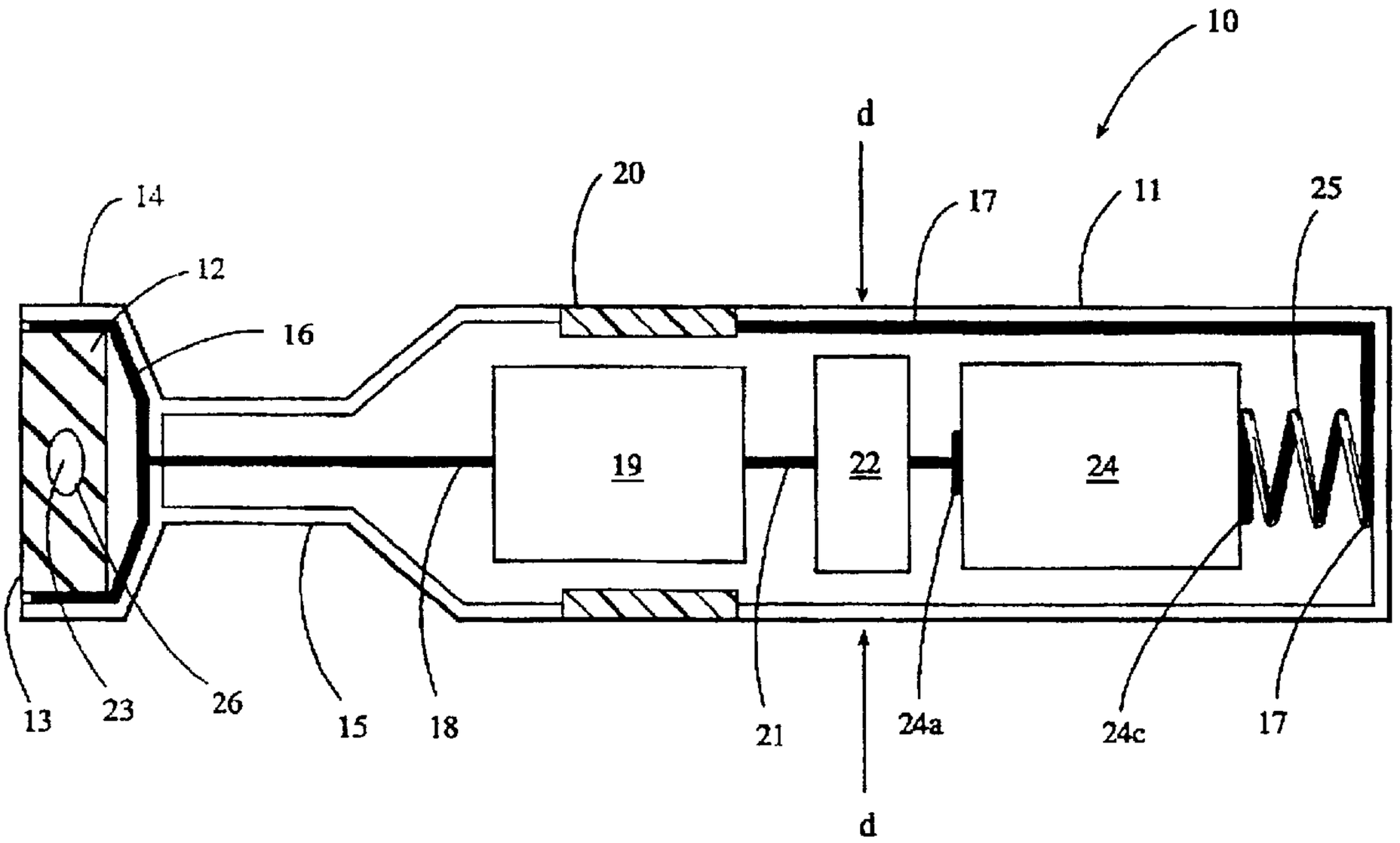

Figure 1

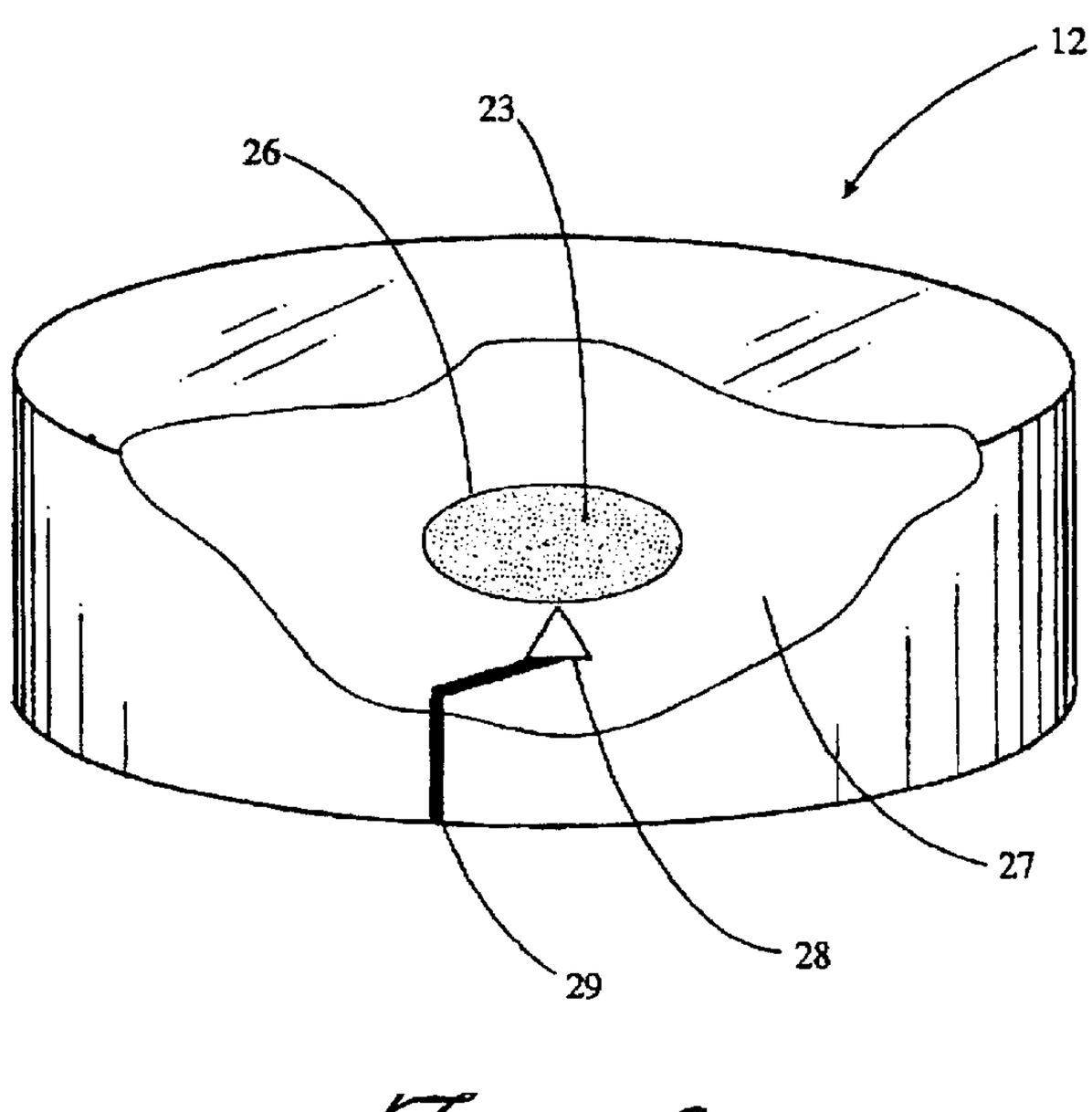

Figure 2

ELECTROKINETIC DRUG DELIVERY APPARATUS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to the transdermal electrokinetic mass transfer of medication into a diseased tissue and, more specifically, to a portable apparatus for the iontophoretic delivery of medication across the skin and incorporation of the medication into diseased tissues and blood vessels adjacent to the delivery site. The apparatus provides a new method for treating and managing diseases presenting cutaneous lesions.

2. Prior Art

Iontophoresis has been employed for several centuries as a means for applying medication locally through a patient's skin and for delivering medicaments to the eyes and ears. The application of an electric field to the skin is known to greatly enhance the skin's permeability to various ionic agents. The use of iontophoretic transdermal delivery techniques has obviated the need for hypodermic injection for many medicaments, thereby eliminating the concomitant problems of trauma, pain and risk of infection to the patient.

Iontophoresis involves the application of an electromotive force to drive or repel oppositely charged ions through the dermal layers into a target tissue. Particularly suitable target tissue include tissues adjacent to the delivery site for localized treatment or tissues remote therefrom in which case the medicament enters into the circulatory system and is transported to a tissue by the blood. Positively charged ions are driven into the skin at an anode while negatively charged ions are driven into the skin at a cathode. Studies have shown increased skin penetration of drugs at anodic or cathodic electrodes regardless of the predominant molecular ionic charge on the drug. This effect is mediated by polarization and osmotic effects.

Regardless of the charge of the medicament to be administered, a iontophoretic delivery device employs two electrodes (an anode and a cathode) in conjunction with the patient's skin to form a closed circuit between one of the electrodes (referred to herein alternatively as a "working" an "application" or "applicator" electrode) which is positioned at the delivered site of drug delivery and a passive or "grounding" electrode affixed to a second site on the skin to enhance the rate of penetration of the medicament into the skin adjacent to the applicator electrode.

Recent interest in the use of iontophoresis for delivering drugs through a patient's skin to a desired treatment site has stimulated a redesign of many of such drugs with concomitant increased efficacy of the drugs when delivered transdermally. As iontophoretic delivery of medicaments become more widely used, the opportunity for a consumer/patient to iontophoretically administer a transdermal dosage of medicaments simply and safely at non-medical or non-professional facilities would be desirable and practical. Similarly, when a consumer/patient travels, it would be desirable to have a personal, easily transportable apparatus available which is operable for the iontophoretic transdermal delivery of a medication packaged in a single dosage applicator. The present invention provides a portable iontophoretic medicament delivery apparatus and a unit-dosage

medicament-containing applicator electrode which is disposable and adapted for use with the apparatus for self-administering medicament.

SUMMARY OF THE INVENTION

The present invention discloses a portable iontophoretic transdermal or transmucoscal medicament delivery apparatus and a unit dosage medicament applicator electrode adapted for use with the apparatus for the self-administration of a unit dose of a medicament into the skin. The apparatus is particularly suited for the localized treatment of herpes infections. Recurrent herpetic infections (fever blisters or herpes labialis) are very common and usually involve the mucocutaaeous juncture. The established treatment for recurrent herpetic lesions (oral or genital) has been primarily supportive; including local topical application of anesthesia. Severe cases have been treated with systemic Acyclovir® (Zovirax Burroughs-Wellcome). Some cases the condition is managed with prophylactic long-term dosing administration with a suitable antiviral agent at great expense. Systemic treatment of acute herpetic flare-ups may reduce the normal 10–12 day course of cutaneous symptoms into a 6–8 day episode. Topical treatment of lesions with Acyclovir® has not been as effective as in vitro studies would suggest. A compound which is not presently available to clinicians but has demonstrated significant anti herpetic activity is 5-iodo-2 deoxyuridine (IUDR). Both of those agents have shown limited clinical efficacy when applied topically to the herpetic lesion. It is the present inventor's contention that the limited efficacy of topical administration previously observed is, at least in part, due to the poor skin penetration of these medicaments when applied topically. The present invention provides improved transdermal delivery of these medicaments and demonstrates improved clinical results in the case of Herpes.

Oral Herpes (most commonly Herpes simplex I infection) as well as genital Herpes (usually Herpes Simplex II infection) afflict many people, cause discomfort, shame, and may contribute to more severe and costly illnesses such as cervical cancer, prostate cancer, and perinatal blindness from herpetic conjunctivitis. The present invention discloses a portable, user-friendly transdermal delivery device and a method for using the device with Acyclovit® (or similar antiviral agent) to greatly benefit these afflicted patients. The present inventor has constructed embodiments of this device and conducted human clinical trials which clearly demonstrate improved therapeutic efficacy using iontophoretically administered antiviral agents when compared to unassisted topical application of the agent.

It is an object of the present invention to provide an iontophoretic medicament delivery apparatus which is portable and operable for self-administration of medicament into the skin of a person.

It is another object of the present invention to provide an improved iontophoretic transdermal drug delivery apparatus having a medicament-containing application electrode which disperses a single dosage and is disposable and non-reusable.

It is a feature of the present invention that the iontophoretic medicament delivery apparatus is easily maneuverable and operable when hand-held.

It is another feature of the present invention that the iontophoretic medicament delivery apparatus is battery powered and conveniently transported by a person.

It is a further feature of the present invention that the iontophoretic medicament delivery apparatus employs a

tactile electrode which is in electrical contact with the skin of a user's hand when the apparatus is held is the user's hand, obviating the need for a separate grounding electrode connector or wire.

It is still another feature of the present invention that the iontophoretic medicament delivery apparatus is adapted to be operable with a disposable medicament containing applicator electrode which applicator electrode includes an absorbent, inert, non-corrosive portion containing a therapeutic agent.

It is yet another feature of the present invention to provide an embodiment of an iontophoretic transdermal delivery device wherein the disposable iontophoretic medicament-containing applicator electrode is adapted for releasable attachment to use with a hand-held base assembly housing a grounding electrode.

It is yet another feature of the present invention that the disposable iontophoretic medicament applicator electrode include indicator means operable for enabling a user to determine when the medicament within the removable applicator electrode has been released in delivery and/or depleted.

It is yet another feature of the present invention that the circuitry employed in the disposable iontophoretic medicament applicator include current limiting means operable for limiting the electrical current .flowing between the surface of the applicator and the skin to less than about one milliampere per square centimeters of application electrode skin-contacting surface.

It is another advantage of the present invention that the iontophoretic medicament delivery apparatus employs a disposable application electrode which conducts the electrical current to the tissue through the solution in which the medicament is dissolved.

It is still another advantage of the present invention that the improved disposable iontophoretic medicament applicator is inexpensive, safe to use and greatly increases the therapeutic efficacy of a medicament administered thereby.

The apparatus in accordance with the present invention provides a means for topically administering medicament directly and with high efficiency into a diseased tissue thereby providing a novel method for treating clinical conditions presenting mucocutaneous symptoms and particularly mucocutaneous Herpes Simplex viral eruptions and sequelle associated therewith.

The above objects, features and advantages of the invention are realized by the improved monopolar iontophoretic medicament applicator which is easily transportable. The applicator employs a detachable medicament containing application electrode. The objects, features and advantages of the invention will become apparent upon consideration of the following detailed disclosure of the invention, especially when it is taken in conjunction with the accompanying drawings wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevational plan view of the iontophoretic medicament delivery apparatus showing the circumferential tactile ground electrode on the outer surface of the base housing and a disposable iontophoretic application electrode;

FIG. **2** is a side elevational view of the disposable non-reusable iontophoretic application electrode with a portion broken away to view the medicament dose packet;

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** shows, in side elevation, a preferred embodiment of the hand-held iontophoretic transdermal medicament

delivery apparatus of the present invention. The apparatus, indicated generally by the numeral **10**, has an elongate base assembly **11** the major portion of which is preferably formed of plastic and shaped to conform to and comfortably fit within a users hand. An applicator electrode module **12**, containing a unit dose of medicament **23**, is releasably attached to a applicator electrode receptacle **14** on the distal end of the base assembly **11**. The application electrode **12** is preferably a "clip-on" type of electrode similar in configuration to an electrocardiogram electrode. In the drawing presented in FIGS. **1** and **2**, electrically conductive elements such as wires and busses are presented as heavy lines. A wire **16** provides electrical connection between the applicator electrode receptacle **14** and wire **18** within the neck **15** of the base assembly **11**. Connecting wire **18**, in turn, provides electrical connection between the wire **16** and the current driver unit **19** housed within the base assembly **11**. A conductive tactile electrode **20** forms a portion of the exterior skin-contacting surface of the base assembly **11** preferably circumferentially enclosing a portion of the base housing or it may be interrupted or discontinuous on the outer surface. The tactile electrode **20** is in electrical communication with the cathode **24**C of battery **24** by means of a buss **17** and conductive urging spring **25** which secures the battery in position within the base assembly **11**. For the self-administration of medicament a user must have skin contact with the tactile electrode **20** for the unit to operate. Current driver **19** underlies the cathodic (ground) tactile electrode **20** and is electrically connected via wire **21** to a voltage multiplier **22**. The voltage multiplier **22** receives low voltage power from the anode **24***a* of the battery power source **24** and increases the available voltage for presentation to the application electrode **12**. The battery **24** is preferably a size AA or AAA. Battery **24** is held in place by an electrically conductive biasing spring **25** and ensures that electrical power is available at the application electrode **12** when the user grasps and holds the base housing **11** of the apparatus **10** thereby touching the cathodic tactile electrode **20**. The application electrode **12** and the tactile electrode **20** thus form a closed circuit in series with the user's skin.

When current flows across the user's skin to the application electrode in response to an applied voltage the current promotes and hastens the penetration of the medicament **23** contained in a reservoir **26** within the working electrode **12** into the skin. The polarity of the working electrode **12** is preferably unidirectional to promote the above described penetration without requiring a separate grounding electrode. The working application electrode **12** will be described in greater detail below.

The base assembly **11** of apparatus **10** serves as a housing to the aforesaid components as a handle. The portion of the base assembly **11**, exclusive of the tactile electrode, is preferably made of a plastic such as polyethylene, acrylonitrile, butadiene, styrene or similar durable plastic. The battery portion **24** is connected to a voltage multiplier **22** which steps up the voltage supplied by the battery **24** and applies the stepped up voltage to the current driver **19**. Current driver **19** presents a defined current and voltage output at the application electrode **12** the value of the current, which may be empirically determined being sufficient to drive the medicament through the porous, open-celled material **27** (FIG. **2**) within the application electrode interposed between the skin contacting surface **13** and reservoir **26** containing the unit dose medicament and penetrate the patient's skin. The circuitry limits the maximum current available to the application electrode to preferably to less than about one milliampere per two square centimeters

of the skin-contacting surface area **13** of the application electrode **12**. However, depending upon working electrode's 12 skin-contacting surface **13** configuration, the current level can vary from about 0.1 to about 1.2 milliamps. Currents ranging between 0.1 ma to 5 ma have been used clinically by the present inventor, but the higher currents caused the user minor discomfort and, with chronic use over time, may produce untoward effects.

FIG. **2** shows a preferred embodiment of the iontophoretic medicament-containing application electrode **12**. The application electrode **12** is preferably disposable and non-reusable and is suitable, for example, for transdermally delivering antiviral agents such as Acyclovir® for the treatment of cold sores or genital herpes. The size of the skin-contacting surface **13** of application electrode **12** may vary to accommodate specific clinical applications. The application electrode **12** is detachably housed within a recess within the receptacle **14** which recess presents an electrically conductive interior surface to complete the electrical flow path from the connecting wires **18** and **16** to a conductive element **29** within the application electrode. The electrical current from the current driver **19** is conducted through conductive inner surface of the application electrode receptacle **14** to the electrically conductive element **29** within the applicator electrode which element **29** is in electrical contact with the inner surface of the receptacle in contact therewith to drive the medicament **23** or treatment agent through the open-celled sponge-like matrix material **27** and through the user's skin (not shown). The medicament or treatment agent **23** is contained within a rupturable polymer reservoir **26** until dispensed during treatment. A slight exertion of pressure or squeezing of the reservoir **26** against reservoir puncture means **28** releases the medicament or treatment agent into an open-celled sponge-like material **27** within the application electrode for iontophoretic delivery into the patient's skin. Medicament **23** release can occur at the time of application of upon peruse compression of the electrode **12**. Application electrode **12** can be advantageously designed to include a stripping portion adapted so that upon removal of the application electrode **12** from the electrode receptacle **14** a protruding stripping portion (not shown) scrapingly strips the conductive coating from the conductive support aim **29** to prevent reuse of the disposable electrode **12**. Application electrode **12** is intentionally packaged with a single dose packet or reservoir **26** of treatment agent or medicament **23**. In addition to the medicament, the reservoir **26** can include a coloring agent, such as iodine, which turns dark blue upon contact with starch in the open-celled material to visibly indicate that the unit dose encapsulation has been used Other suitable coloring agents can include pH indicators, wet saturation indicators or oxidizable pigments.

The open-celled sponge-like material **27** surrounding resevoir **26** should be inert to the medicament or treatment agent being employed, as well as being non-corrosive and stable when in contact with the treatment agent. Suitable materials include plastic pads, such as polyethylene, paper or cotton, porous ceramics, open-celled porous polytetrafluoroethylene, polyurethane and other inert plastics, and open-celled silicone rubber, such as may be employed with vertically aligned medicament-containing tubes. A typical medicament that can be contained within the rupturable polymer reservoir **26** is xylocaine or similar topical anesthetic. The disposable electrode **12** possesses the advantages of preventing leaching or migration of the medicament from within the rupturable polymer reservoir, no attendant loss of efficacy, a long shelf life and little or no electrode corrosion. A suitable electrical control circuit for use in the iontophoretic medicament delivery apparatus **12** is shown in U.S. patent application, Ser. No. 07/579,799, filed Sep. 10, 1990, now U.S. Pat. No. 5,160,316, and hereby specifically incorporated by reference herein in pertinent part.

EXPERIMENTAL CLINICAL TRIALS

The inventor has conducted a clinical study using a prototype iontophoretic device in accordance with the present invention for the treatment of cold sores. The clinical response was promising. A second independent, qualified investigator, a board-certified Urologist, conducted a study using the present apparatus and method for treating male genital herpes lesions with encouraging results. Table 1 summarizes data (discussed below) supporting the claim to unexpected clinical benefits treating disease with this novel method. The method and medicament application device when used together for treating these common, embarrassing, and previously not easily-treatable ailments provide surprising advantages.

The embodiment of the device shown in FIG. **1** and described hereinabove is a improvement over the prototype used in the clinical study, which was a larger unit, not user friendly, which required physically connecting wires to the patient's body which created anxiety, and could not be used without attending personnel. Notwithstanding design, the apparatus used in the clinical study summarized in Table 1 employed electronics similar to the apparatus described herein and was used to optimize the clinical performance of the embodiment **12** of the device described herein.

TABLE 1

STAGE I TREATMENT RESULTS

RESPONSE	IUDR	ACYCLOVIR ®	TOTALS
No response	1	1	2
Some response	1	3	4
Major response	26	42	68

The study included a control situation wherein seven patients were found who had simultaneous concurrent herpes lesions at separate locations on their bodies. In each case one lesion was treated with iontophoretic application of antiviral agent (Acyclovir® or IUDR) and the other lesion was treated in the standard method employed in the prior art comprising repeated topical application of the same antiviral agent. The iontophoretically enhanced treated lesion received a single 10–15 minute treatment. All iontophoretically treated lesions demonstrated resolution in 24 hours and none of the unassisted topically treated lesions demonstrated a similar response. The results for the control group are summarized in Table 2.

TABLE 2

	CONTROL GROUP RESULTS		
	No response	Some resp.	Major resp.
IUDR			
Treated lesion	0	0	7
Control lesion	5	2	0
ACYCLOVIR ®			
Treated lesion	0	0	1
Control lesion	1	0	0

The clinical studies included patient volunteers with full informed consent who suffered from recurrent cold sores. The study demonstrated greatest treatment efficacy if the herpes lesion received iontophoretic treatment within 36 hours of lesion onset. The treatment incorporated an electrode saturated with Acyclovir® ointment (ZOVIRAX®) or IUDR (STOXIL®) Ophthalmic drops as supplied by the manufacturer. Thus mounted Anodic electrode of the prototype system was used for a 10–15 minute application directly to the lesion with the average current setting of 0.2 ma-0.6 ma which was well tolerated by all patients.

The lesion was evaluated in 24 hours. In 92% of the **[**iontophoreticlly**]** *iontophoretically* treated cases (×70 lesions treated) a major response was noted. A major response was categorized by resolution of pain in <6 hours and lesion crusted and healing within 24 hours. The normal course of cold sores involves an average period of 10–12 days before resolution and healing occurs. The present apparatus and clinical method for treatment of mucocutaneous Herpes Simplex (type I and Type II) eruptions presented herein have been described and performed with excellent results. This novel user friendly apparatus in combination with the disclosed clinical treatment method presents a very effective new treatment for Herpes Simplex eruptions.

While the invention has been described above with references to specific embodiments thereof, it is apparent that many changes, modifications and variations in the materials, arrangements of parts and steps can be made without departing from the inventive concept disclosed herein. For example, an impregnated conductive gel can also be used to as medicament containing medium to increase the physical stability and the tissue adhering characteristics of the electrode. Accordingly, the spirit and broad scope of the appended claims is intended to embrace all such changes, modifications and variations that may occur to one of skill in the art upon a reading of the disclosure. All patent applications, patents and other publication cited herein are incorporated by reference in their entirety.

What I claim is:

[1. An iontophoretic drug delivery device for personal use for self administering a medicament into a person's skin, said device comprising a base assembly and a detachable applicator electrode wherein said base assembly comprises:

(a) a case having an elongate, substantially cylindrical outer surface having a size and shape adapted to be comfortably grasped within a person's hand and wherein at least a portion of said outer surface is a tactile electrode formed of as electrically conductive material;

(b) a bipolar electrical power means having a first pole and a second pole; said electrical power means being enclosed within said case and wherein said first pole is in electrical communication with said tactile electrode;

and wherein said applicator electrode comprises a porous matrix portion, a module containing a unit dose of medicament, an electrically conductive working electrode and attachment means adapted for releasably attaching said application electrode to said base assembly to provide electrical connection between said working electrode and said second pole of said electrical power means and wherein said iontophoretic delivery device is operable for releasing said medicament to permeate said porous matrix portion and delivering said medicament from said porous matrix portion to a portion of the person's skin in contact with matrix portion of said applicator electrode.**]**

[2. The device in claim **1** wherein said unit dose of medicament is encapsulated within a rupturable reservoir.**]**

[3. The device in claim **2** wherein said rupturable reservoir further contains a visualizing agent which is released when said reservoir is ruptured thereafter providing a visual signal indicating the release of medicament.**]**

[4. The device of claim **2** wherein the porous matrix portion is selected from the group consisting of polyethylene, paper, cotton, polytetrafluoroethylene, open-celled polyurethane, open-celled silicone and ceramic.**]**

[5. The device of claim **3** wherein the porous matrix portion is selected from the group consisting of polyethylene, paper, cotton, polytetrafluoroethylene, open-celled polyurethane, open-celled silicone and ceramic.**]**

6. An electrokinetic drug delivery device for personal use for self-administering a medicament into a person's skin, said device comprising a base assembly and a detachable applicator electrode wherein said base assembly comprises:

(a) a case having an elongate, substantially cylindrical outer surface having a size and shape adapted to be comfortably grasped within a person's hand and wherein at least a portion of said outer surface includes a tactile electrode formed of an electrically conductive material;

(b) a bipolar electrical power means having a first pole and a second pole, said electrical power means being enclosed within said case and wherein said first pole is in electrical communication with said tactile electrode; and

(c) a current driver and a voltage multiplier in electrical contact with said second pole;

and wherein said applicator electrode includes a porous matrix portion, a module containing a unit dose of medicament for release into and permeation of the porous matrix portion, an electrically conductive working electrode and attachment means adapted for releasably attaching said applicator electrode to said base assembly to provide electrical connection between said working electrode and said second pole of said electrical power means through said current driver and voltage multiplier and wherein, upon release of the medicament and permeation of the porous matrix portion, said electrokinetic delivery device being operable to electrokinetically deliver said medicament from said porous matrix portion to a portion of the person's skin in contact with the porous matrix portion of said applicator electrode.

7. A device according to claim 6 wherein said unit dose of medicament is encapsulated within said module, said module comprising a rupturable reservoir.

8. A device according to claim 7 wherein said rupturable reservoir further contains a visualizing agent which is released when said reservoir is ruptured to provide a visual signal indicating the release of medicament.

9. A device according to claim 8 wherein the porous matrix portion is elected from the group consisting of polyethylene, paper, cotton, polytetrafluoroethylene, open-celled polyurethane, open-celled silicone and ceramic.

10. A device according to claim 7 wherein the porous matrix portion is selected from the group consisting of polyethylene, paper, cotton, polytetrafluoroethylene, open-celled polyurethane, open-celled silicone and ceramic.

11. A device according to claim 6 including a visualizing agent carried by said device for indicating one-time usage of the device.

12. An electrokinetic delivery device for personal use and self-administration of a medicament to an individual's treatment site, comprising:

a base assembly having a portion thereof shaped for manual manipulation by a hand of the individual, and a tactile electrode formed of electrically conductive material and exposed on said base assembly for electrical contact with the individual's hand;

a self-contained power source within said base assembly and in electrical contact with said tactile electrode;

an applicator electrode;

attachment means for releasably attaching the applicator electrode to the base assembly, said applicator electrode including a porous matrix and a unit dose of an electrokinetically transportable medicament encapsulated in a rupturable reservoir, said porous matrix lying in electrical contact with said power source and having a surface for contact with the individual's treatment site;

a current driver and a voltage multiplier carried by said base assembly and electrically coupled to said power source and providing a defined current and voltage output at said applicator electrode, said current driver limiting the current available to the applicator electrode within a range of 0.05–0.6 milliamps per cm^2;

said device being operable, upon rupture of said reservoir, to release the medicament to permeate the porous matrix and electrokinetically transport said medicament from said applicator electrode to the individual's treatment site in contact with said surface in response to completion of an electrical circuit with said power source via at least a portion of the individual's hand through said tactile electrode and said applicator electrode surface and the individual's treatment site.

13. A device according to claim 12 including an indicator affording a visual indication of medicament release into the porous material.

14. A device according to claim 12 including means for preventing reuse of the applicator electrode.

15. A device according to claim 12 wherein said current driver limits the current available to the applicator electrode to less than 0.6 milliamp per cm^2.

16. A device according to claim 12 wherein said applicator electrode comprises a disposable applicator electrode.

17. A device according to claim 12 wherein said base assembly is elongated and has opposite ends, said tactile electrode being exposed through said shaped portion, said applicator electrode being carried by said base assembly adjacent one of said ends thereof and being exposed therefrom for contact with the individual's treatment site.

18. A device according to claim 17 wherein said shaped portion comprises a cylindrical surface having said tactile electrode exposed along said cylindrical surface.

19. A device according to claim 12 including an indicator affording a visual indication of medicament release into the porous material, said base assembly being elongated and having opposite ends, said tactile electrode being exposed through said shaped portion, said applicator electrode being carried by said base assembly adjacent one of said ends thereof and being exposed therefrom for contact with the individual's treatment site.

20. A device according to claim 12 including means for preventing reuse of the applicator electrode, said base assembly being elongated and having opposite ends, said tactile electrode being exposed through said shaped portion, said applicator electrode being carried said base assembly adjacent one of said ends thereof and being exposed therefrom for contact with the individual's treatment site.

21. An electrokinetic delivery device for personal use and self-administration of a medicament to an individual's treatment site, comprising:

a base assembly having a portion thereof shaped for manual manipulation by a hand of the individual, and a tactile electrode formed of electrically conductive material and exposed on said base assembly for electrical contact with the individual's hand;

a self-contained power source within said base assembly and in electrical contact with said tactile electrode;

an applicator electrode including a porous matrix for interposition between said base assembly and the treatment site and a unit dose of an electrokinetically transportable medicament encapsulated in a rupturable reservoir, said porous matrix lying in electrical contact with said power source, said porous matrix having a surface for contact with the individual's treatment site;

a current driver and a voltage multiplier carried by said base assembly and electrically coupled to said power source and providing a defined current and voltage output at said applicator electrode, said current driver limiting the current available to the applicator electrode within a range of 0.05–0.6 milliamps per cm^2,

said device being operable, upon rupture of said reservoir, to release the medicament to permeate the porous matrix and electrokinetically transport said medicament from said applicator electrode to the individual's treatment site in contact with said surface in response to completion of an electrical circuit with said power source via at least a portion of the individual's hand through said tactile electrode and said applicator electrode surface and the individual's treatment site.

22. A device according to claim 21 including an indicator affording a visual indication of medicament release into the porous material.

23. A device according to claim 21 including means for preventing reuse of the applicator electrode.

24. A device according to claim 21 wherein said applicator electrode comprises a disposable applicator electrode, said base assembly being elongated and having opposite ends, said tactile electrode being exposed through said shaped portion, said applicator electrode being located adjacent one of said ends thereof and exposed therefrom for contact with the individual's treatment site.

25. A device according to claim 24 wherein said shaped portion comprises a cylindrical surface having said tactile electrode exposed along said cylindrical surface.

26. A device according to claim 24 including an indicator affording a visual indication of medicament release into the porous material.

27. A device according to claim 24 including means for preventing reuse of the applicator electrode.

28. A device according to claim 27 including an indicator affording a visual indication of medicament release into the porous material.

29. A device according to claim 21 including a visualizing agent carried by said device for indicating one-time usage of the device.

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