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From the 1950's



2016

Device Description

Trade/Proprietary Name:	Puremedy's Original Healing Salve
Common Name:	Dressing, wound, drug
Classification Regulations:	Unclassified
Product Code:	FRO
Classification Panel:	General & Plastic Surgery

Device description: Topical wound healing salve

Puremedy Original Healing Salve is used for the management of wounds including:

- ☐ Pressure sores
- ☐ Diabetic ulcers
- ☐ Leg ulcers
- ☐ Donor sites and graft sites
- ☐ Surgical wounds
- ☐ Skin abrasions and lacerations
- ☐ 1st and 2nd degree burns
- ☐ Trauma wounds
- ☐ Minor cuts
- ☐ Minor scalds and 1st and 2nd degree burns
- ☐ Abrasions
- ☐ Lacerations



Today's goals

To demonstrate that the Original Healing Salve would be appropriately categorized as a Class II device.

In addition I will demonstrate:

- Safety and Efficacy
- minimal to negligible public health risk
- evidence of indications for use
- antibacterial effectiveness



- Bactericidal
- Kills large spectrum of harmful bacteria including MRSA
- ~ 90% killed within the first 1 minute
- All microorganisms killed within 4 hours

 <p>ACCU Bio-Chem LABORATORIES</p> <p>INDUSTRIAL . PHARMACEUTICAL COSMETIC . FOOD . ENVIRONMENTAL 5406 San Fernando Rd. #201 Glendale, CA 91203 Tel: 818-547-3221.Fax: 818-547-3021</p>	<p>To: Puremedy</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Report No.</td> <td style="padding: 2px;">PR091914-02</td> </tr> <tr> <td style="padding: 2px;">Report Date:</td> <td style="padding: 2px;">Oct 14, 2014</td> </tr> <tr> <td style="padding: 2px;">Page:</td> <td style="padding: 2px;">1 of 1</td> </tr> </table>	Report No.	PR091914-02	Report Date:	Oct 14, 2014	Page:	1 of 1
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ANTIMICROBIAL EFFICACY / TIME-KILL ANALYSIS REPORT

Product Description: Original Healing Salve Laboratory Reference No.: 4244077

Microorganisms	Inoculum / g	Colony Forming Units (Viable Microbes) Recovered from Each Gram of Product								
		1 min	2 min	5 min	10 min	30 min	1 hr	2 hrs	4 hrs	8 hrs
Staph. aureus (ATCC 6538)	1.0×10^6	126,000	43,000	14,700	4500	1300	520	180	< 10	< 10
Methicillin Res. S. aureus (ATCC43300)	1.2×10^6	97,000	29,000	10,500	2300	780	160	< 10	< 10	< 10
Streptococcus pyogenes (ATCC 19615)	1.1×10^6	61,000	18,000	12,200	3800	150	< 10	< 10	< 10	< 10
Escherichia coli (ATCC 8739)	1.0×10^6	84,000	37,000	17,600	5100	830	370	90	< 10	< 10
Salmonella typhimurium (ATCC 14028)	1.1×10^6	52,000	12,000	8,400	1050	< 10	< 10	< 10	< 10	< 10
Enterobacter Cloacae (ATCC 13047)	1.0×10^6	47,000	14,000	7,600	960	< 10	< 10	< 10	< 10	< 10
Klebsilla Pneumoniae (ATCC 13883)	1.0×10^6	56,000	26,000	11,300	3150	80	< 10	< 10	< 10	< 10
Pseudomonas aeruginosa (ATCC 9027)	1.1×10^6	72,000	38,000	16,900	3220	910	430	150	< 10	< 10
Burkholderia cepacia (ATCC 25416)	1.0×10^6	39,000	29,000	12,100	1280	170	< 10	< 10	< 10	< 10
Candida albicans (ATCC 10231)	1.1×10^5	31,000	8,500	4,200	2480	1240	310	120	< 10	< 10
Vegetative A. niger (ATCC 16404)	1.2×10^5	28,000	6,800	3,500	1560	860	180	< 10	< 10	< 10

(ATCC = American Type Culture Collection; < 10 is the statistical expression of no microbial recovery for the plate count test method) (NR= No Significant Reduction from the initial count)

CONCLUSION: 99.9 percent of the inoculated microorganisms were killed within 4 hours of coming in contact with the product.


 Approved By: _____
 Laboratory Director

Bacteriostatic

1. Bacteria cannot grow in the presence of the salve
2. Proves the device does not require a preservative

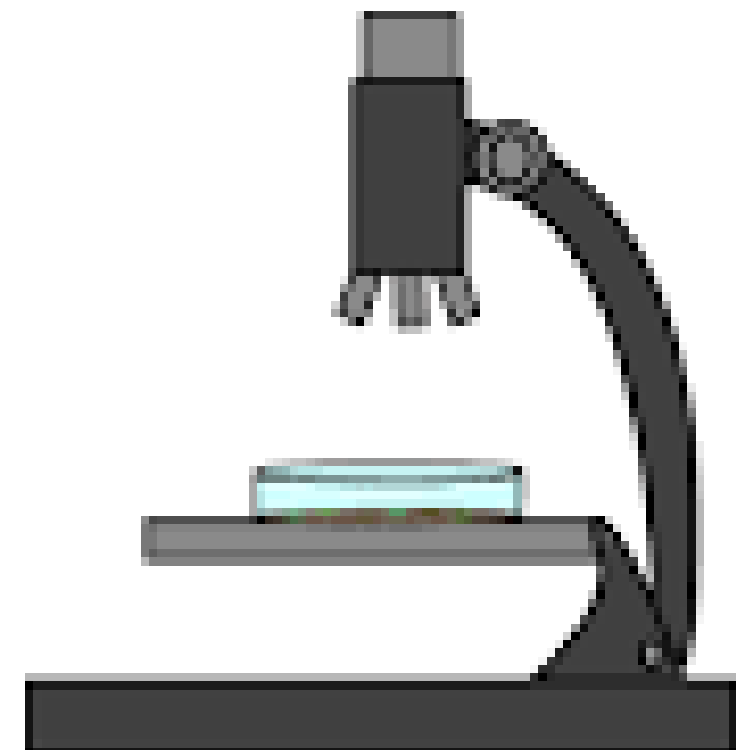
	To: Joni Siegel Puremedy	
INDUSTRIAL . PHARMACEUTICAL COSMETIC . FOOD . ENVIRONMENTAL 5406 San Fernando Rd. #201 Glendale, CA 91203 Tel: 818-547-3221.Fax: 818-547-3021	Report No.	PM060810-01
	Report Date:	July 12, 2010
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MICROBIOLOGICAL TEST REPORT

PRESERVATIVE EFFICACY TEST

Product Description: Original Healing Salve
 Setup Date: 06/08/2010 Date Completed: 07/12/2010
 ACCU Reference No.: 1052737

Microorganisms	Inoculum / g	Colony Forming Units / gram				
		Time 0	Day 7	Day 14	Day 21	Day 28
E. coli	1.0×10^6	TNTC	< 10	< 10	< 10	< 10
S. aureus	1.0×10^6	TNTC	< 10	< 10	< 10	< 10
Ent. cloacae	1.05×10^6	TNTC	< 10	< 10	< 10	< 10
Kl. pneumoniae	1.1×10^6	TNTC	< 10	< 10	< 10	< 10
Ps. aeruginosa	1.05×10^6	TNTC	< 10	< 10	< 10	< 10
B. cepacia	1.0×10^6	TNTC	< 10	< 10	< 10	< 10
Ps. fluorescens	1.0×10^6	TNTC	< 10	< 10	< 10	< 10
Ps. putida	1.05×10^6	TNTC	< 10	< 10	< 10	< 10
C. albicans	1.0×10^5	TNTC	< 10	< 10	< 10	< 10
A. niger	1.0×10^5	TNTC	4,590	3,940	2,680	190



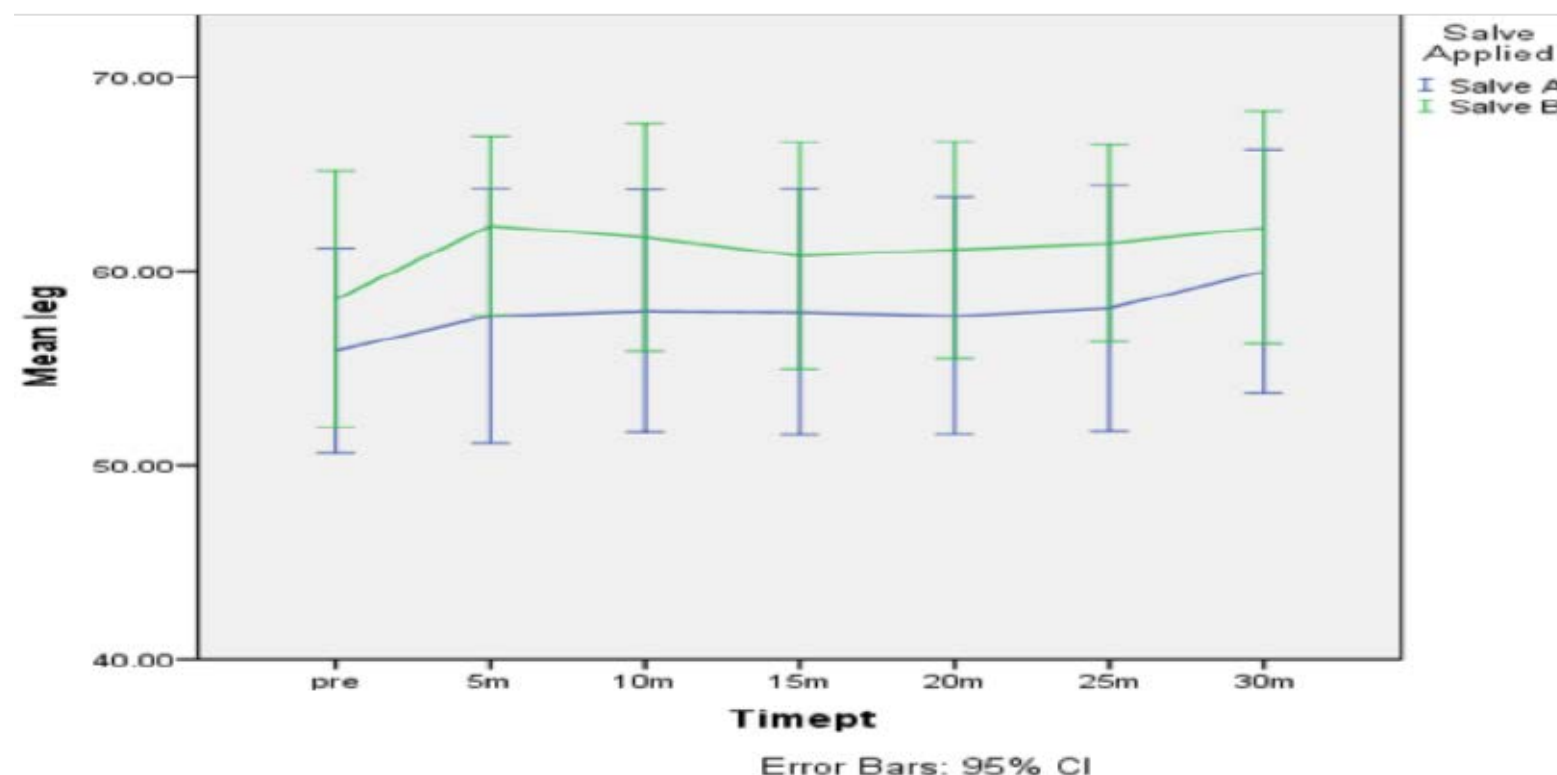
Effects of a Herbal/Homeopathic Topical Salve on Cutaneous Oxygenation in Type @ Diabetes

Ryan Bradley, ND, MPH; Andrew Erlandsen, ND; Jan Taylor; Doug Hanes, PhD
Helfgott Research Institute, National College of Natural Medicine | Portland, Oregon USA



Method: Using a subcutaneous oxygen monitor from Radiometer, we conducted a randomized, controlled, crossover, triple-masked clinical trial to measure the effects of Original Healing Salve (OHS) on the TcPO₂ in the skin of the lower extremity in sixteen (n=16) generally healthy adults with type 2 diabetes without peripheral artery disease.

Conclusion: The Puremedy® Original Healing Salve increased TcPO₂ after 30 minutes in people with type 2 diabetes, (between 4% and 13%) however the contributions of the herbal and homeopathic ingredients remain unclear.



Autolytic Debridement

- **An embedded splinter**
- **3 mls of salve applied at night with a bandaid**
- **The next morning the splinter appears on the bandaid, drawn out from skin overnight**



Tested and Potential Mechanisms of Puremedy's Original Healing Salve for Wound Care

Mechanisms:

- “Drawing” action - autolytic debridement
- Increase blood circulation and oxygen
- Bacteriostatic and Bactericidal
- Provides moist wound healing environment
- Protects wound bed

Observed Mechanisms

Dr. Matt Montee of Advantage Wound Care in El Segundo, CA

- Stimulates Microphages and Fibroblasts
- Reduces colonization count
- Improve wound bed moisture retention
- Improve wound collagen matrix
- Speeds up epithelialization phase and formation of granulation tissue
- Anti-inflammatory action

Hypothesized Mechanism of action - Antibacterial properties (requires further study)

- It is proposed that the ointment fundamentally traps the bacteria in a water free air free environment and interfering with the. Additionally, because of the thick viscosity of the tree extracts, the device appears to be interfering somehow with communication between bacteria.

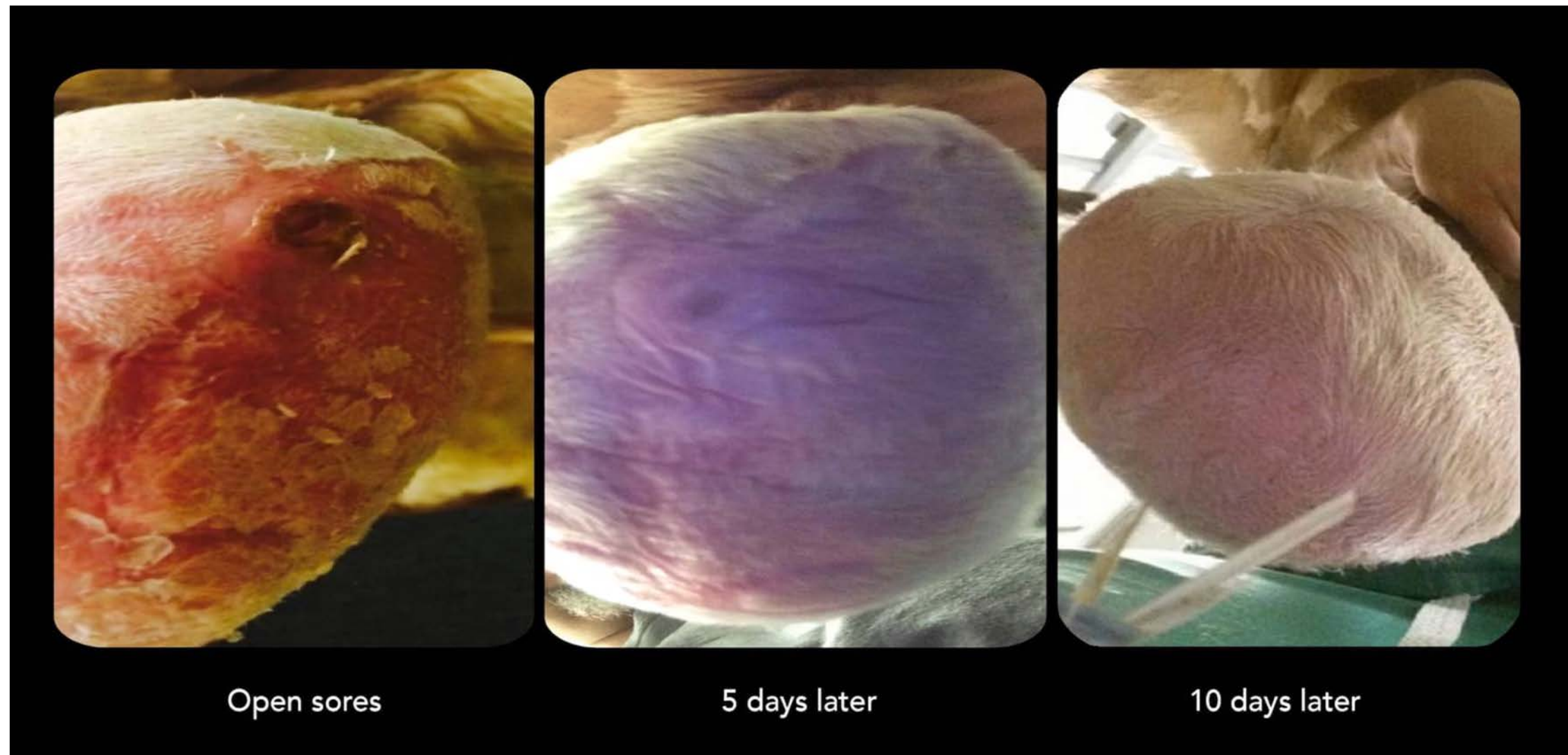




“Dudley” was rescued by The Gentle Barn. He had a severed foot and now successfully wears a prosthetic, thanks to Puremedy’s Original Healing Salve



“Dudley” the cow: Wound healing progression



Wounds from prosthetic

wounds on his stump;
necrotic and damaged
tissue

After 5 days

wound, necrotic and
damaged tissue
resolved

After 10 days

Dudley's stump is growing
hair back on apparently new
fully functioning skin

“Little Bear” dog wound

healing progression over 4 weeks



Dog bite - wound healing progression

Only treated with Original Healing Salve



After 15 minutes



Day 4



Day 12



Day 22



Today

Conclusion

SAFETY: Based on the indications for use, I believe there is a minimal to risk to health from this product.

- Over 1 million users and 150 years - no adverse events reported
- Minimal side effects, <1% allergic or sensitive
- 100% food grade ingredients, all GRASE

EFFICACY: Puremedy's Original Healing Salve salve provides:

- antibacterial action
- a moist wound healing environment
- autolytic debridement
- increased circulation and oxygen
- protection for the wound bed
- anti-inflammatory action
- resolution of chronic wounds in case studies
- antimicrobial power that should not contribute to the formation of new "superbugs". More research is necessary

1960 - This salve saved my Mom's life from a nearly fatal hospital acquired infection following a severe allergic reaction to penicillin



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