These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00679562
		Study Code:	LACAC_L_03648
Generic drug name:	Lactic Acid	Date:	05/Feb/2009

Title of the study:	Skin Irritation : Prophetic Patch Test of Lactacyd Radiance		
Investigator(s):	Ubonthip Nimmannit, Ph.D. Faculty of Pharmaceutical Sciences, Chulalongkorn University		
Study center(s):	Faculty of Pharmaceutical Sciences, Chulalongkorn University Bangkok, Thailand		
Publications (reference):	N/A		
Study period: Date first subject enrolled: 23 Mar 2008 Date last subject completed: 24 Apr 2008		Phase of development: Clinical Study Phase II	
Objectives:	To evaluate the potential of the products in eliciting adverse skin reaction		
Methodology:	Single centre, Open-labelled, Prospective Study		
Number of subjects:	Planned: 200	Randomized: -	Treated: 200
Evaluated:	Efficacy/Pharmacodynamics: -N/A	Safety: Allergic reaction	Pharmacokinetics: N/A
	Allergic reaction will be observed after patch removal at 15-30 minutes at day 3. Grading of an allergic reaction is followed to The International Dermatitis Research Group (ICDRG) No Reaction 0 Mild Reaction +1 Moderate Reaction +2 Sever Reaction +3		
Diagnosis and criteria for inclusion:	Healthy volunteers with 1. Individuals age : 18-60 years old 2. Test area should have a healthy or normal skin 3. Individuals free of any systemic or dermatological disorder which, in the opinions of the investigative personnel would interfere with the study results or increase the risk of adverse reaction 4. Not currently use of steroids or any medication during the test 5. Patients will to participate in the study with written informed consent.		

Investigational product: Dose: Administration:	Lactacyd Confidence Fresh Radiance Dilute with distilled water 1:100 Skin application at the back	
Duration of treatment: 1 day		Duration of observation: 3 days
Reference therapy: Dose: Administration:	Distilled water, Lactacyd Fragrance Free Dilute with distilled water 1:100 Skin application at the back	
Criteria for evaluation:		
Safety:	Allergic reaction will be observed after patch removal at 15-30 minutes. The patch will be attached for 3 days. After removal, allergic reaction will be observed. Grading of an allergic reaction is followed to The International Dermatitis Research Group (ICDRG) No Reaction 0 Mild Reaction +1 Moderate Reaction +2 Sever Reaction +3	
Statistical methods:	One-way ANOVA	
Summary: Safety Result	Lactacyd Confidence Fresh Radiance tested with 200 healthy volunteers demonstrates neither any allergic reactions nor adverse events compared with distilled water and Lactacyd Fragrance Free.	
Date of report:	08 Jul 2008	