



## Niravi - Lidocaine 4% topical patch

Niravi–Lidocaine 4% patch is an OTC topical patch with a unique formula developed and manufactured by Sparsha Pharma USA, Inc. (Sparsha). Sparsha’s formulation is a high quality matrix type drug in adhesive formulation that makes an extremely thin, user friendly patch compared to other brands. Niravi-Lidocaine 4% patch enables consistent drug delivery up to 24 hours by stable adherence on skin.

### Niravi

Niravi is Sparsha’s brand name for pain relief patch.

Niravi stands for “Pain removal” in Sanskrit. Niravi is manufactured by Sparsha, Oceanside, CA.

- Up to 24 hours consistent drug delivery
- Minimizes local skin damage with longer application and breathable non-woven backing cloth
- User friendly – Easily applied without direct touch
- 24 hours application duration makes application time easy to remember
- Fits on the body with ultra thin non-woven backing cloth; hardly noticeable
- Earth friendly – High drug utilization and less wasteful after use



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## Sparsha

Sparsha is a pharmaceutical company located in Oceanside, California that specializes in transdermal/topical film products. Sparsha has the capability to take products from formulation development to commercial production.

Sparsha produces the Lidocaine 4% Patch under Current Good Manufacturing Practice (cGMP). Sparsha supplies the same Lidocaine 4% patch for other brands (Theracare, Asperflex, etc.) in the U.S.

## **Comparison**

### Sparsha Patch (Niravi)

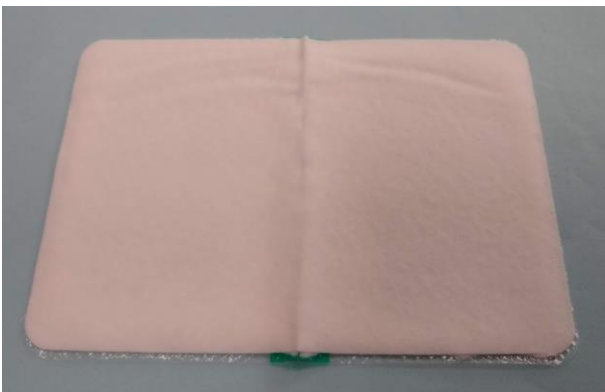
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Sparsha uses high quality, thin nonwoven backing cloth to support drug adhesive formulation. It is a thinner patch compared with any other Lidocaine patch available on the market. This characteristic contributes to better adhesion and higher rate of drug utilization for drug delivery. A patch is placed on two release liners which makes application easier for user to avoid touching adhesive. Sparsha patch formulation is constructed based on US FDA recognized materials.  
(Application duration: up to 24 hour)

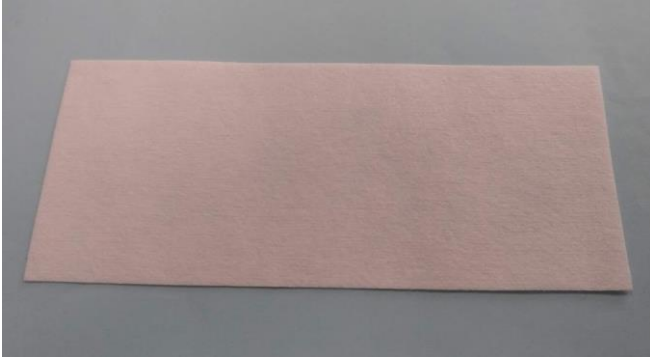
### Hydrogel Patch available on market

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Hydrogel patch gives cooling sensation upon user application. The backing cloth is thick and flexible, but the adhesion nature is weaker in general.  
(At most 8 hours application on label)

### Matrix Patch available on market

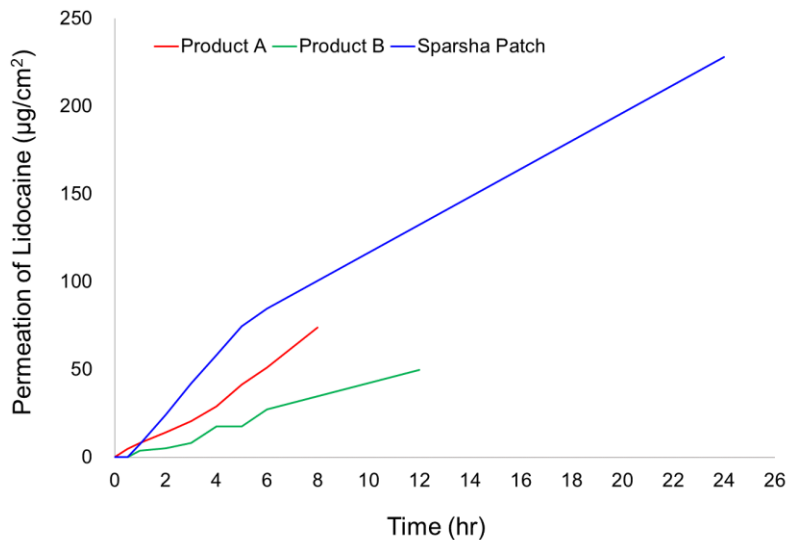


Due to thick and non-stretchable non-woven cloth, the patch tends to be peeled off from the corner or edge by body movement or cloth contact in general.

(8-12 hours application on label)

### **Drug Delivery**

The drug delivery characteristics of the Sparsha Lidocaine 4% patch was compared with commercially available Lidocaine 4% patches by *in vitro* human cadaver skin permeation study (Product A: Hydrogel type, Product B: Matrix type), and result was shown in Figure 1.



**Figure 1 Lidocaine permeation through human skin**

Sparsha patch showed higher drug delivery compared with both commercial products. From the data, continuous drug delivery was confirmed for up to 24 hours.



### **Patch adherence**

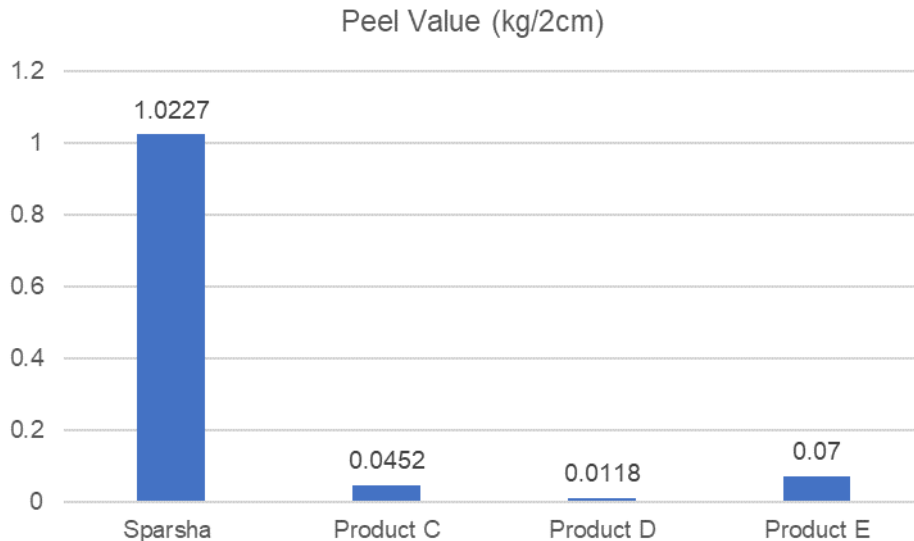
Peel adhesion force of Sparsha Lidocaine 4% Patch was compared with commercially available Lidocaine 4% patches (Product C, Product D and Product E).

#### Products

Product	Duration of application on label
Sparsha Lidocaine 4% Patch	Up to 24 hours
Product C	Up to 12 hours
Product D	At most 8 hours
Product E	Up to 12 hours

Adhesion test: 180-degree peel test

Sample width: 2cm



**Figure 2 Peel adhesion of Lidocaine 4% Patches**

Sparsha Lidocaine 4% patch showed much higher adhesion compared with other commercially available products.



Sparsha Lidocaine 4% patch was applied on human volunteers to confirm its adhesion.

(The volunteer applied Sparsha Lidocaine 4% Patch for 24 hours, most of the patch area was adhering even after 24 hours.)

There was no pain upon removal of patch after 24 hours.



### Shelf life

2 years from the date of manufacture

