



## Technical Data Sheet

# Levulinic Acid HP, CDMF, USDMF

### Applications

Levulinic Acid is widely used in the pharmaceutical industry and specially for Topical products (i.e. Transdermal patches).

Following is a list of key applications:

- Emollient
- Emulsifier
- Excipient
- Humectant
- Penetration enhancer



### General Information

Pharmacopeia Status	: In-house product
CAS No.	: 123-76-2
EC No.	: 204-649-2
Appearance/Description	: Colourless to light yellow liquid / Solid.
Molecular Formula	: $C_5H_8O_3$
Molecular Mass	: 116.11 g/mol

### Marketed Formulation

Buprenorphine transdermal patches and more...

### Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

### Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of elemental impurities as per ICH Q3D

### Pack Mode

500 gm & 2.5 kg plastic container

### DMF (Drug Master File)

- USDMF registered product (DMF # 31434)
- CDMF registered product (CDE # F20190000626)

### Stability and Storage Conditions

Stable under recommended storage conditions. Keep container tightly closed in a cool & dry, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

### Safety and Handling Information

Use personal protective equipment while handling material and avoid contact with skin and eyes. In case of eye contact rinse thoroughly with plenty of water for at least 15 minutes. In case of skin contact wash with soap and water. Avoid dust formation, breathing vapours, mist or gas. Ensure adequate ventilation. If inhaled, move person into fresh air and consult with physician.

## Product Specifications (In-house)

Description	Colourless to light yellow liquid / solid
Identification (By IR)	Conforms to structure
Purity (By GC)	Min. 98.0%
Cadmium (Cd)	0.5ppm max.
Mercury (Hg)	1.5ppm max.
Lead (Pb)	0.5ppm max.
Arsenic (As)	0.15ppm max.

## Shipping Information

### By Sea, Air and Road

Nature: Non Hazardous

See the Material Safety Data Sheet on [www.finarchemicals.com](http://www.finarchemicals.com)

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For more information contact : [deepaklodhiya@finarchemicals.com](mailto:deepaklodhiya@finarchemicals.com)

## Finar Limited

### CORPORATE OFFICE & WORKS

184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej  
Bavla Highway, Sanand, Ahmedabad - 382110. Gujarat, INDIA.  
t: +91-2717-616717 | e: [sales@finarchemicals.com](mailto:sales@finarchemicals.com)  
[www.finarchemicals.com](http://www.finarchemicals.com)

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