



## Technical Data Sheet

# Diethyl phthalate

IP, Ph.Eur., USP-NF

### Applications

Diethyl phthalate is used as a plasticizer for film coatings on tablets, beads and in solid oral dosage forms.



### General Information

Pharmacopeia Status	: IP, Ph.Eur., USP-NF
CAS No.	: 6106-24-7
EC No.	: 212-773-3
Appearance/Description	: Clear, colourless or very slightly yellow, oily liquid.
Molecular Formula	: C <sub>12</sub> H <sub>14</sub> O <sub>4</sub>
Molecular Mass	: 222.24 g/mol

### Marketed Formulation

- Carbamazepine extended-release 200 mg tablets
- Didanosine delayed release 125 mg tablets
- Isosorbide mononitrate extended release 30 mg tablets & many more...

### Quality and Regulatory Support

- GMP and ISO certification
- EXCI PACT 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 sub-visible particles

### Pack Mode

- 1 kg, 2.5 Litre, 2.5 kg glass bottle
- 25 kg HDPE container

### Stability and Storage Conditions

Keep away from heat and sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not breathe dust.

### Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Diethyl phthalate is irritant to the skin, eyes and mucous membranes. Protective clothing, eye protection and nitrile gloves are recommended. Diethyl phthalate should be handled in a fume cupboard or a well-ventilated environment; a respirator is recommended.

## Pharmaceutical Specifications

Description/Appearance	A clear, oily liquid, colourless or very slightly yellow (IP, USP-NF, Ph.Eur)
Solubility	Practically insoluble in water, miscible with ethanol & in ether (Ph.Eur ,IP ,USP-NF)
Identification A (By IR)	To comply the test (IP)
Identification A ( By Relative density, 20°C)	1.117-1.121 (Ph.Eur)
Identification by IR	To comply the test (USP-NF)
Identification B (By Relative density, 25°C)	1.117 to 1.121 (IP)
Identification B (By Refractive index, 20±0.5°C)	1.500 to 1.505 (Ph.Eur)
Specific gravity (20°C)	Between 1.118 to 1.122 (USP-NF)
Identification C (By TLC)	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (IP)
Identification C (By IR)	To comply the test (Ph.Eur)
Refractive index,20° C	Between 1.500 to 1.505 (USP-NF)
Identification D (By Chemical test)	The solution becomes yellow or brownish-yellow and shows green fluorescence (IP)
Identification D (By TLC)	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution (Ph.Eur)
Identification E (By Chemical test)	The solution becomes yellow or brownish-yellow and shows green fluorescence (Ph.Eur)
Appearance of solution	The substance to be examined is clear and not more intensely coloured than reference solution YS6 (IP, Ph.Eur)
Acidity	Not more than 0.1ml of 0.1M sodium hydroxide is required to change the colour of the indicator to pink (IP, Ph.Eur, USP-NF)
Related substances	1.0% max. (IP, Ph.Eur)
Water	Not more than 0.2% (IP, USP-NF ,Ph.Eur)
Sulphated ash	Not more than 0.1% (IP, Ph.Eur)
Residue on ignition	Not more than 0.02% (USP-NF)
Assay	99.0%-101.0% (IP Ph.Eur, USP-NF)

## Regulatory Information

Included in the FDA Inactive Ingredients Database (oral capsules, delayed action, enteric coated and sustained action tablets). Included in non-parenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

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

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## Shipping Information

**By Sea, Air and Road**

Nature: Non Hazardous

## Finar Limited

### CORPORATE OFFICE & WORKS

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**passion &  
innovation**  
our commitment !