

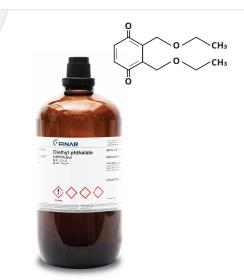


Technical Data Sheet

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 : C₁₂H₁₄O₄
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
- 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 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

A clear, oily liquid, colourless or very slightly yellow (IP, USP-NF, Ph.Eur) Practically insoluble in water, miscible with ethanol & in ether (Ph.Eur ,IP ,USP-NF) To comply the test (IP) 1.117-1.121 (Ph.Eur) To comply the test (USP-NF)
(Ph.Eur ,IP ,USP-NF) To comply the test (IP) 1.117-1.121 (Ph.Eur)
To comply the test (IP) 1.117-1.121 (Ph.Eur)
1.117-1.121 (Ph.Eur)
To comply the test (USP-NF)
1.117 to 1.121 (IP)
1.500 to 1.505 (Ph.Eur)
Between 1.118 to 1.122 (USP-NF)
The principal spot in the chromatogram obtained with the test solution
corresponds to that in the chromatogram obtained with reference solution (IP
To comply the test (Ph.Eur)
Between 1.500 to 1.505 (USP-NF)
The solution becomes yellow or brownish-yellow and shows green
fluorescence (IP)
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)
The solution becomes yellow or brownish-yellow and shows green
fluorescence (Ph.Eur)
The substance to be examined is clear and not more intensely coloured than
reference solution YS6 (IP, Ph.Eur)
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)
1.0% max. (IP, Ph.Eur)
Not more than 0.2% (IP, USP-NF ,Ph.Eur)
Not more than 0.1% (IP, Ph.Eur)
Not more than 0.02% (USP-NF)
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.

Shipping Information

By Sea, Air and Road Nature: Non Hazardous

See the Material Safety Data Sheet on www.finarchemicals.com

Note: The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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Chemistry is our passion & innovation our commitment!