

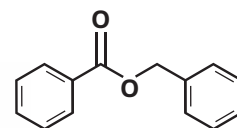


Benzyl benzoate

IP, BP, Ph.Eur., USP, CDMF

Applications

Benzyl benzoate is widely used as a pharmaceutical excipient in various formulations as a plasticizer, solubilizing agent and solvent. The preferred route of application is Parenteral (i.e., Microcapsules, Microspheres) and Topical (i.e. Gel, Cream) dosage forms.



General Information

Pharmacopeia Status	: IP, BP, Ph.Eur., USP
CAS No	: 120-51-4
EC No.	: 204-402-9
Appearance/Description	: Clear, colorless, oily liquid having a slight aromatic odor
Molecular Formula	: C ₁₄ H ₁₂ O ₂
Molecular Mass	: 212 g/mol

Marketed Formulations

- Fulvestrant injection
- Progesterone injection
- Estradiol injection
- Testosterone undecanoate depot (injection)
- & 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
- Low Endotoxin suitable for parenteral application
- Control of TAMC & TYMC
- Control of pathogens
- Control of sub-visible particles

Pack Mode

- 500 ml, 1 Litre, 2.5 Litre glass bottle
- 25 Litre plastic jerry can

DMF (Drug Master File)

CDMF registered product (CDE # F20190000461)

Stability and Storage Conditions

Benzyl benzoate is stable when stored in tight, well-filled, light resistant containers. Exposure to excessive heat (above 40 °C) should be avoided.

Safety and Handling Information

Benzyl benzoate may be harmful if ingested, and is irritating to the skin, eyes, and mucous membranes. Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection, gloves, and a respirator are recommended. It is recommended that Benzyl benzoate is handled in a fume cupboard. Benzyl benzoate is flammable.

Pharmaceutical Specifications

Description	Clear, colorless, oily liquid having a slight aromatic odor (USP, CDMF, IP, BP, Ph.Eur)
Assay	99.0% - 100.5% (USP, CDMF, IP, BP, Ph.Eur)
Solubility	Practically insoluble in water and glycerin. Miscible with alcohol, ether, methylene chloride and fatty and essential oils and chloroform (USP, CDMF, IP, BP, Ph.Eur)
Identification A (By IR)	IR Spectra of the sample should be concomitant with IR spectra of the corresponding standard (BP, Ph.Eur, USP, CDMF)
Identification B (By Chemical test)	Dried precipitate should melt between 121°C to 124°C (BP, Ph.Eur)
Limit of Aldehydes (As benzaldehyde)	NMT 0.05% (USP, CDMF)
Specific gravity, 25°C	1.116 - 1.120 (USP, CDMF)
Relative density, 20°C	1.113 - 1.118 (IP)
Relative density, 20°C	1.118 - 1.122 (BP, Ph.Eur)
Congeeing temperature	NLT 18.0°C (USP, CDMF)
Congeeing temperature	Not below 17.0° C (IP)
Boiling point	About 320°C (BP, Ph.Eur)
Freezing point	Minimum 17.0°C (BP, Ph.Eur)
Refractive index, 20° C	1.568 - 1.570 (IP, BP, Ph.Eur, USP, CDMF)
Sulphated ash	NMT 0.1% (IP, BP, Ph.Eur)
Acidity	NMT 1.5 mL of 0.02N sodium hydroxide should be required to restore the pink color (USP, CDMF)
Acidity	Not more than 0.2 mL of 0.1M sodium hydroxide should be required to change the color of the indicator to pink (BP, Ph.Eur)
Total aerobic microbial count	NMT 100 cfu/ml (In-house)
Total combined yeast and molds count	NMT 10 cfu/ml (In-house)
Bacterial endotoxins	NMT 0.25 EU/ml (In-house)
E.coli	Absent/ml (In-house)
Salmonella	Absent/10ml (In-house)
Staphylococcus aureus	Absent/ml (In-house)
Pseud. aeruginosa	Absent/ml (In-house)
Purity (By GC)	NLT 99.8% (In-house)
Any individual impurity (By GC)	NMT 0.10% (In-house)

Regulatory Information

Included in the FDA Inactive Ingredients Database (IM injections and oral capsules). Included as an active ingredient in Non-parenteral medicines licensed in the UK and the Canadian List of Acceptable Non-medicinal Ingredients.

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

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For more information contact : deepaklodhiya@finarchemicals.com

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN No.: UN3082

Transport Hazard class: 9

Packing group: II

Finar Limited

CORPORATE OFFICE & WORKS

184-185-186/P, Vill:Chacharwadi Vasna, Bavla 8km milestone, Sarkhej
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