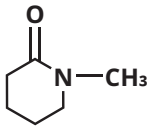
Technical Data Sheet

N-Methyl-2-Pyrrolidone

Ph.Eur., USP-NF



Applications

N-Methyl-2-Pyrrolidone is an organic bipolar solvent. It is widely used as a solublizer in various pharmaceutical formulations during processing of various dosage forms including solid orals and other NDDS products. It is removed during processing and does not remain in the final product.

General Information

Pharmacopeia Status	:	Ph.Eur., USP-NF
CAS No.	:	872-50-4
EC No.	:	212-828-1
Appearance/Description	:	Clear colorless liquid.
Molecular Formula	:	C_5H_9NO
Molecular Mass	:	99.13 g/mol

Marketed Formulation

- Doxycycline hyclate gel
- Leuprolide acetate depot injection
- Florfenicol IV solution (Veterinary medicine)

  & 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
- Low Endotoxin suitable for parenteral application
- Control of TAMC & TYMC
- Control of sub-visible particles

Pack Mode

1 Litre, 2.5 Litre glass bottle

Stability and Storage Conditions

Store it in cool place. Keep container tightly closed in a dry and well-ventilated place.

Safety and Handling Information

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure -obtain special instructions before use.

Pharmaceutical Specifications

Description /Appearance	A clear colourless to a slightly yellow liquid with a boiling point of about 202° and refractive index of about 1.469 (USP-NF, Ph.Eur)
Solubility	Miscible with water, with alcohol and with most organic solvents including alcohol, ketones, and aromatic and chlorinated hydrocarbons (USP-NF ,Ph.Eur)
Identification A (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard. (USP-NF)
Organic impurities : individual impurity	NMT 0.1% (USP-NF, Ph.Eur)
Organic impurities : total impurities	NMT 0.3% (USP-NF, Ph.Eur)
Alkalinity	NMT 8.0 mL of 0.02 M hydrochloric acid should require (USP-NF)
Clarity of solution	The sample should show the same clarity as that of water, or its opalescence should not be more pronounced than that of the reference suspension (USP-NF)
Colour of solution	The sample should not be more intensely colored than the comparison solution (USP-NF)
Water (By KF)	NMT 0.1% (USP-NF, Ph.Eur)
Boiling point	About 204°C (Ph.Eur)
Relative density	about 1.034 (Ph.Eur)
Refractive index	about 1.469 (Ph.Eur)
Alkalinity	Not more than 8 mL of 0.02M hydrochloric acid should require (Ph.Eur)
Total aerobic microbial count	NMT 100 cfu/ml (In-house)
Total Yeast & mold count	NMT 10 cfu/ml (In-house)
Bacterial endotoxins	NMT 2.5 EU/ml (In-house)

Shipping Information

By Sea, Air and Road
Nature: Non Hazardous

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

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