

Description

Naproxen sodium is a nonsteroidal anti-inflammatory agent that also has analgesic activity. It is used in the symptomatic treatment of acute and chronic rheumatoid arthritis, osteoarthritis, primary dysmenorrhea and for relief of mild to moderate pain. It is the sodium salt of naproxen, which is more rapidly absorbed; used for rapid analgesia.

Chemical name: (-)-6-methoxy- α -methyl-2-naphthaleneacetic acid, sodium salt

Chemical formula: $C_{14}H_{13}NaO_3$

Specifications

USP (Current Edition) Requirements

Range

Identification	passes test
Assay, %	98.5 - 102.0
Specific optical rotation, ($^{\circ}$)	-17.0 - -15.3
Chromatographic purity	
Total impurities, %, max.	2.0
Largest impurity, %, max.	0.5
Heavy metals, ppm, max.	20
Loss on drying, %, max.	1.0
Organic volatile impurities	meets requirements
Toluene, ppm, max.	500
Particle size, %, \leq 250 microns, min.	95
Free naproxen, %, max.	1.0
SMBA, ppm, max.	50
Chiral purity %, S min.	98
HPLC impurities	
Hydrolyzed naproxen, %, max.	0.2
Linear naproxen, %, max.	0.2
Chloronaproxen, %	< 0.10
Other single impurity, %	< 0.10
Total impurities, %, max.	0.50

Shipping Information

Bulk naproxen sodium is sold in 50 kg (net) fiber drums

Caution: Federal law prohibits dispensing naproxen sodium in the U.S.A. without appropriate Food and Drug Administration (FDA) approval. For manufacturing, processing, or repackaging only.

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Chemical Registration Numbers

CAS: 26159-34-2

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