

## SPECIFICATION

<b>Product Name:</b> Montelukast Sodium IP Grade
<b>Chemical Formula:</b> C <sub>35</sub> H <sub>35</sub> ClNNaO <sub>3</sub> S
<b>CAS Number:</b> 151767-02-1
<b>Molecular Weight:</b> 608.18 g/mol
<b>Appearance:</b> A white to pale yellow powder
<b>Odor:</b> Odorless

### Chemical Composition

Parameter	Unit	Typical Value	Specifications Min./Max.
Identification: By IR	-	Complies	IR absorption spectrum should be identical to that of working standard. Should give positive test.
Test for sodium	-	Complies	
Specific optical rotation	°	+103.0°	+95.0° to +106.0°
Water (By K.F.)	%	0.3%w/w	NMT 3.0% w/w
Heavy metals	PPM	<20 PPM	NMT 20 PPM
Related substances (By HPLC)			
a) Montelukast sulfoxide isomers (Sulfoxide + Sulfone)	%	0.04%w/w	NMT 0.3%w/w
b) Montelukast Styrene (vinyl)	%	0.22%w/w	NMT 0.3%w/w
c) Any other individual impurity	%	0.03%w/w	NMT 0.3%w/w
d) Total impurities	%	0.36%w/w	NMT 1.0%w/w
Residual solvent			
Methanol	PPM	157 PPM	NMT 3000 PPM
Toluene	PPM	47 PPM	NMT 890 PPM
Assay (HPLC, OAB)	%	99.2%w/w	98.0% to 102.0%w/w

### **Physical Properties**

- Solubility: Soluble in water. Soluble in ethanol. Soluble in methanol. Soluble in acetone. Insoluble in ether. Soluble in chloroform. Soluble in methylene chloride.

### **Shelf Life & Storage**

- Shelf Life: 3 years from date of manufacture under recommended storage.  
- Storage Conditions: Store in a tightly closed, light-resistant, moisture-resistant container in a cool, dry, and well-ventilated place, protected from moisture, light, excessive heat, and contamination

### **Applications**

- Use: Widely used in the manufacture of pharmaceutical formulations for the prevention and long-term management of asthma and allergic rhinitis, and for the prevention of exercise-induced bronchoconstriction.  
- Dosage: Depends on the patient's age, indication, and dosage form. The following are general therapeutic dosage guidelines for finished pharmaceutical products.

### **Packaging**

- Standard Packing: 25 Kgs HDPE drum or as per customer requirement.  
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

\* Specifications are based on the manufacturer's provided specifications.