

SPECIFICATION

Product Name: Pregabalin IP Grade
Chemical Formula: C ₈ H ₁₇ NO ₂
CAS Number: 148553-50-8
Molecular Weight: 159.23 g/mol
Appearance: White to off white crystalline powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min./Max.)
Identification by IR	-	Complies	The IR absorption spectrum of the sample should concordant with spectrum of the working standard.
Specific optical rotation (C=1%w/v in water)	°	+10.89°	+10° to +12°
Sulphated Ash	%	0.04%	NMT 0.1%
Heavy metals	PPM	<20 PPM	NMT 20 PPM
Loss on drying (At 105°C for 3hr)	%	0.08%	NMT 0.5%
Assay by HPLC (On dry basis)	%	99.41%	98.0% to 102.0%
Related substances (By HPLC)			
1) Lactam Impurity	%	Not detected	NMT 0.5%
2) Any individual single maximum impurities	%	0.31%	NMT 0.5%
3) Total Impurities	%	0.63%	NMT 1.0%
Enantiomeric purity by HPLC (R-Pregabalin)	%	0.01%	NMT 0.5%

Physical Properties

- Solubility: Soluble in water. Soluble in ethanol. Insoluble in acetone. Soluble in methanol.

Shelf Life & Storage

- Shelf Life: 3 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a cool, dry place at 20–25°C (controlled room temperature). Protect from moisture, excessive heat, and direct sunlight. Keep the container tightly closed in the original, properly labeled container and store in a well-ventilated area to maintain product quality and stability.

Applications

- Use: Widely used for the treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, spinal cord injury, and fibromyalgia.
- Dosage: Depends on the approved indication, patient age, kidney function, and clinical response. It should only be used under the supervision of a qualified healthcare professional.

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.