

SPECIFICATION

Product Name: Paracetamol IP Grade
Chemical Formula: C ₈ H ₉ NO ₂
CAS Number: 103-90-2
Molecular Weight: 151.16 g/mol
Appearance: White Crystalline Powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min/Max)
Identification			
B) By UV absorbance at about 249 nm	-	0.442	0.427 to 0.453
C) Colour Test	-	Complies	A violet color develops which does not turn red.
D) Test for acetyl groups	-	Complies	A blue color develops at the junction of two drops after 1 or 2 min. the color intensifies and persists for a short time.
Heavy metals	PPM	Less than 10 PPM	NMT 10 PPM
Sulphated Ash	%	0.05%	NMT 0.10%
Loss on drying	%	0.16%	NMT 0.50%
Assay (on dried basis)	%	99.8%	NMT 99.0% and NMT 101.0% of C ₈ H ₉ NO ₂
Related Substances (By HPLC)			
4- Chloroacetanilide	PPM	BDL (<0.5 PPM)	NMT 10 PPM
4- Aminophenol	PPM	BDL (<1.15 PPM)	NMT 50 PPM
4- Nitrophenol	%	BDL (<0.0009%)	NMT 0.05%

Any other impurity	%	BDRL (<0.01%)	NMT 0.05%
Total of other impurities	%	BDRL (<0.01%)	NMT 0.1%

Physical Properties

- Solubility: Slightly soluble in water. Freely soluble in ethanol. Soluble in acetone. Slightly soluble in ether. Slightly soluble in chloroform.

Shelf Life & Storage

- Shelf Life: 5 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed container in a cool, dry, and well-ventilated place, protected from moisture, humidity, excessive heat, and direct sunlight.

Applications

- Use: Widely used in pharmaceutical formulations as an analgesic (pain reliever) and antipyretic (fever reducer).
- Dosage: Depends on Age and body weight, Severity of pain or fever, Medical condition, Concomitant medications, Regulatory and prescribing guidelines.

Packaging

- Standard Packing: 25 kg woven PP bags with inner liner 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.