

## **RAMRITOL® 60IP- MANNITOL**

### **DEFINITION**

D-MANNITOL, Indian Pharmacopoeia (IP) grade

CAS N° : 69-65-8

EINECS : 200-711-8

White crystalline free-flowing powder, odorless with sweet taste.

### **SPECIFICATIONS**

- **Physico-Chemical Values**

<b>Test Items</b>	<b>Test Methods</b>	<b>Specification</b>
Appearance	IP	White crystalline powder or free-flowing granules
Identification A(IR spectrum)	IP	Conforms
Identification B(Ferric chloride)	IP	Conforms
Identification C(Catechol)	IP	Conforms
Identification D (Melting range)	IP	165°C~170 °C
Appearance in solution	IP	Clear, Colourless
Acidity	IP	0.2 ml max / 5g (NaOH 0.01M)
Specific Optical Rotation (sodium tetraborate)	IP	+23~+25° (Dried substance)
Arsenic	IP	2 ppm Max
Chloride	IP	50 ppm Max
Sulfate	IP	100 ppm Max
Reducing sugars	IP	NLT 12.8mL of 0.05M sodium thiosulphate required
Sorbitol by TLC	IP	Spot less intense than test sample
Sulfated Ash	IP	0.1% Max
Loss on drying	IP	0.5% Max
Assay (HPLC)	IP	98.0%~102.0% on dried basis

## SPECIFICATION

- Typical Values

Particle Size	By Sieve	
>60mesh/ 250µm		10% max

- Microbiological Values

Total Viable Count	1000cfu/g max.
Moulds & Yeasts	100cfu/g max.
Escherichia Coli	Absent in 10g
Salmonella	Absent in 10g

## COMMENTS

The methods used by GNCP may be current IP, ChP or internal validated methods.

## STORAGE

**Requirements:** store at room temperature, in a dry place and in its unopened original packaging.

**Shelf life:** 2 years in its original packaging from manufacturing date.

**Standard packaging (25 kg/bag):**

- Primary packaging: PE bag,
- Secondly packaging: paper bags, carton box or fibre drum.