

# PARENTERALS

# CONTAINERS USED FOR PARENTERALS ARE :-

* GLASS CONTAINER			
Type	Description	Test	General Use
I	Highly resistant, borosilicate glass	Powdered glass	Buffered & unbuffered aq. sol <sup>n</sup> , sterile product
II	Treated soda lime glass	Water attack	Buffered aq. sol <sup>n</sup> below pH 7, dry powder & oleaginous sol <sup>n</sup> .
III	Soda lime glass	Powdered glass	Dry powder and oleaginous solution
IV	General purpose soda lime glass	powdered glass	Not for parenterals.

* PLASTIC CONTAINER	
Type	Uses.
Poly-propylene	Widely used due to high M.P
Poly-ethylene	Ophthalmic products
Polystyrene	Plastic syringes
Flexible PVC	Bags for I.V solution
Nylon & silicon rubber	I.V catheters

* RUBBER CLOSURE	
Type	Example
Elastomers	Natural rubber, Butyl rubber, Neoprene.
Vulcanizing Accelerator	Sulfur.
Activator	ZnO, stearic acid
Fillers	Carbon black, Clay
Antioxidant	Lime stone.
	Dilauryl thiodipropionate

\* DEVICES USED  
 → I.V catheters - Nylon & silicon  
 → Hypodermic needles & syringes

\* PYROGENS  
 → these are lipopolysaccharide  
 → these testing is not imp. in Ophthalmic

\* ISOTONIC SOLUTION  
 when osmotic pressure of sol<sup>n</sup> is equal to 0.9% NaCl or 1.9% Boric acid

# EVALUATION OF PARENTERAL PRODUCTS

LEAKER TEST (Packaging integrity test)	- Only for ampoules, 1% Methylene blue dye & vacuum used.
CLARITY TEST (particulate matter test)	- Instrument like - light scattering (Nephelometer) - light absorption - electrical resistance (counter counter).
PYROGEN TEST	- Fever response in rabbits Limulus test (lal test) - 5 to 10 times more sensitive than rabbit test. Based on gelling of pyrogenic prep <sup>n</sup> .
STERILITY TEST	- Method → Membrane filtration. → Direct inoculation. Incubation - for 2 weeks at 20 to 30 °C