



# Tubes & Filling systems for pharmaceutical pkg.

**Presented by:**

**M.K. Banerjee**

**Dir. Creativity & Innovation (Global)**

**Essel Propack Ltd.**

**July1,2011**

# Fundamental requirements, barrier

- + Based on the Pharma product formulation and active ingredients there in, each and every component of tube inputs to be selected
- + Even though the empty tube look all right, there are no guarantee that on long stability with product filled in, the same tube will survive the aggressive product formulation.
- + For laminated tubes, side seam integrity and shoulder bond are very critical. The same must not deteriorate till the end of product life cycle
- + Print, freshness seal closure must be neutral to the product formulation and active ingredients there in



# Fundamental requirements, regulatory compliance

- + all the polymers must be EC, FDA and DMF approved
- + all the polymers must have a compliance certificate related to REACH, CONEG, Prop-65
- + special compliance certificate such as BPA, Phthalates, nonylphenol, melamine etc.
- + USP -661
- + clean room mfg. facility



# List of Phthalates

<u>Name</u>	<u>Acronym</u>	<u>CAS No.</u>
Dimethyl Phthalate	DMP	131-11-3
Diethyl Phthalate	DEP	84-66-2
Di-n-butyl Phthalate	DBP	84-74-2
Di(2-ethylhexyl) Phthalate	DEHP, DOP	117-81-7
Di(n-octyl) Phthalate	DNOP	117-84-0
Diisononyl Phthlate	DINP	28553-12-0
Diisodecyl Phthalate	DIDP	26761-40-0
Butyl Benzyl Phthlate	BBP	85-68-7

# Basic components of Pharma tubes

- + Tube body: effective Oxygen, moisture and light barrier. Tube collapsibility is preferable but not mandatory for all the product formulations. Surface Print with safe UV or solvent Inks. No ink flaking or delamination
- + Shoulder and neck: HDPE based classic shaped shoulder with short or long nozzle. Orifice size in accordance with product dispensation or application efficacy
- + Freshness seal: either Foil or all plastic barrier laminate. While the seal with the nozzle orifice should be firm, the same should peel off smoothly at consumer end
- + Closure: generally screw on and made out of PP or HDPE. Tamper evident closure is preferable



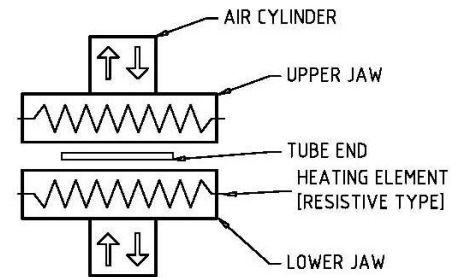
# Tube filling & end seal mechanism

- Filling speed: depending upon the output requirement, filling line speed could be 60, 120, 180, 360 or 600 tubes/min
- Loading/ unloading: for hygiene reason, it is recommended to use auto loading and unloading mechanism
- Vacuum cleaning , Cap tightening, eye mark sensor: these devices are recommended to avoid unnecessary production interruption and quality complain

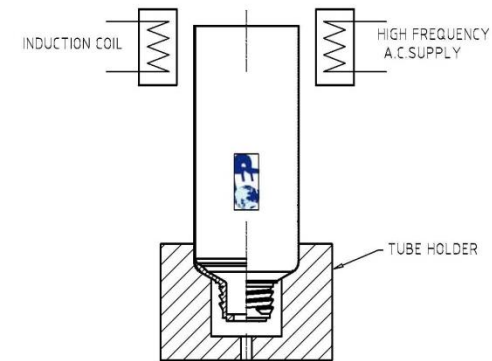


# End seal technology

■ Hot Jaw: filled tube ends are pressed by pair of hot jaws and sealed. Depending upon the speed, there are 2 or 3 pairs of hot jaws used. Demerit of this technology is much lower speed



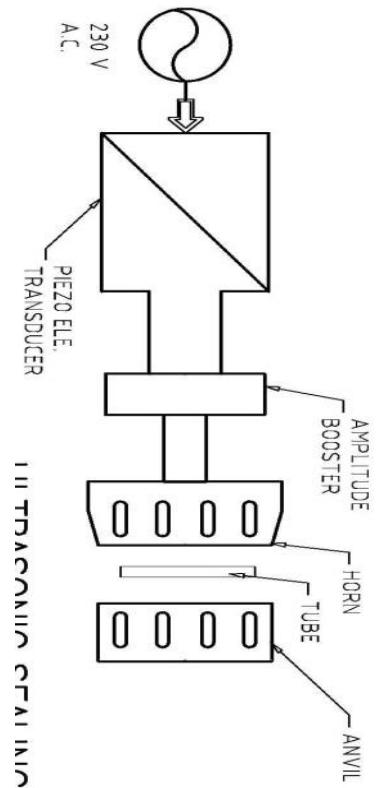
■ High frequency sealing: High frequency energy induces eddy current in the aluminum foil of the composite laminate. Sudden surge of eddy current produce high heat and soften the adjacent polymer. In the next station, soften tube edge is pressed together, code and trimmed.



Cont...

# End seal technology

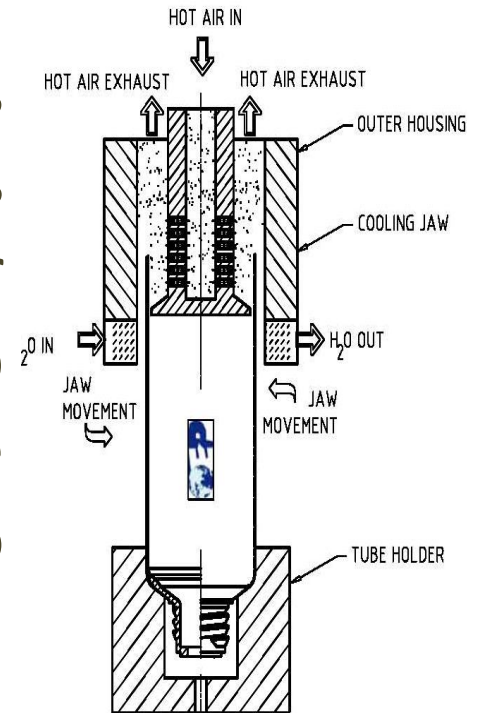
■ Ultrasonic sealing: electrical energy converted in to ultrasonic vibration with the help of Piezoelectric transducer and transfer to the sealing edge. Ultrasonic mechanical vibration create intense local heat and melt the seal interface. Once the energy transfer is over, same Horn & Anvil keep pressing the seal interface till the polymer is solidify. Trimming and coding is done on the next indexing station.



Cont....

# End seal technology

■ Hot Air sealing: Hot air Generator heat up compressed air up to 350° C and injected in to hot air sealing head. Sealing head is design in such a manner that hot air flows only towards the tube inner polymer surfaces. There is a powerful vacuum pump that suck back the hot air. As soon as the seal interface is soften, the tube moves to the next index position and pressed together with the help of a water circulated Jaws. Trimming & coding is done on the next index position



THANK  
YOU