

## TUFLUX TPE TUBING FOR PHARMA PROCESSING

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The guidelines for launching new products and manufacturing those approved products are becoming more stringent on a routine basis. Quality certifications, clean room requirements, forwards and backwards traceability on all components are the new standard for providing FDA-approved products. Part of insuring that quality criteria are being met is to understand how the raw material is created, how it is processed in to a technologically useful processing aid (tube) and then how is that tube tested. Thermoplastic resin is the key ingredient in creating TuFlux tubing. The broad chemistry footprint allows specialized compounders to create unique blends of components (using plasticizers, oils, finishing aids etc) to manipulate the material so that it meets USP Class VI standards but still provides the lower levels of leachables and extractables as well as minimize unwanted biological cell growth.

The raw resin is melted via combination of time, temperature and pressure and formed into a specific shape (single lumens, multi-lumens, oblong geometries) and wall thicknesses to meet the design requirements for the processing equipment of the OEMs. Stripes can be embedded or material can be reinforced with wires or fabric braids to offer further support for high pressure applications as well as reduce cross equipment contamination (due to the colored stripes). Thermoplastic has the unique ability to be re-melted to customize connectors and design solutions in production sites with unique vessel shapes or limited real estate. The combination of proprietary resin and the manufacturing process help to keep the E/L data well below industry limitations as well as reduce the potential growth of bDtBPP.

