

Medication Capsule Thermoforming Process Improvement and Electrostatic Analysis

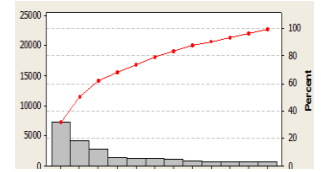
Shane Fogarty - Final Year Mechanical Engineering - Cork Institute of Technology

The manufactured pharmaceutical product medication capsule reduces patient immune system activity and is applied to prevent the rejection of transplanted organs – most prominently in kidney, liver and heart transplants.

Significant product waste and downtime during an industrial thermoforming process - designed to place the medication capsules into a continuous web of blister sheets - are observed and analysed by the author. Static electricity generation is believed to be the root cause of the downtime and waste issues. Static analysis determines that the thermoformer is running at an all time low of 89.5% efficiency. Static related downtime is initially estimated at circa 2.2% or 4,700 minutes - equating to an estimated loss of 40,000 medication capsule packs per year.



Capusle Flow Disruption



Pareto Analysis of Thermoforming Process Downtime



Original Capsule Thermoforming Process Technology and Configuration

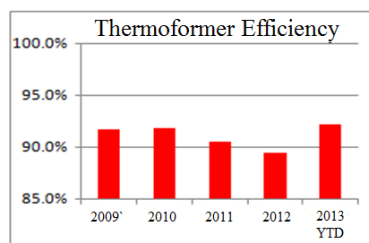
Electrostatic analysis of capsule flow through the thermoforming process in a pharmaceutical environment is undertaken and the theoretical basis of electrostatic generation in an industrial setting formulated by the author. Validation is achieved through the development and implementation of standardised electrostatic measurement procedures, leading to identification and quantification of major areas of electrostatic generation in the thermoforming process. Medication capsule movement is mapped out using a devised process map - static measurement points taken in each area. Temperature and humidity readings are taken and recorded to determine effect on static generated. 56 sets of static data are gathered over a three month period covering different batch sizes, different capsule sizes and product combinations. Varying environmental and storage conditions of the capsules are also taken into consideration.

A systematic design approach is devised and applied to develop a novel medication capsule feeding system. Critical design criteria identified and implemented include static generation reduction, uniform capsule dispersal, good conductive properties, ease of assembly, manufacture and cleaning, low maintenance and FDA approval. A series of designs are developed and Pugh's decision matrix approach utilised to determine optimal design configuration. Optimised 3D model design generation is achieved and novel prototype capsule feeder system fabricated and commissioned. Product quality assurance and regulatory compliance are central to the devised and undertaken validation testing. Prior to entry into commercial use, extensive validation processes and documentation including process failure mode effect analysis, microbiology testing, functionality report, material certificates, manufacturing certificates, working drawings, cleaning standard operating procedures and line clearance standard operating procedures are undertaken and prepared by the author.



Developed Novel Capsule Thermoforming Process Technology and Configuration

The root cause of electrostatic generation is identified and eliminated - resulting in a highly significant increase in medication capsule thermoforming manufacturing efficiency (including secondary savings above initial estimates) of 3%. The redesigned process results in the thermoforming process operating at a four year high of 92.5% efficiency –



Thermoformer Efficiency Four Year High

representing an increase of 70,000 medication capsule packs produced per year, reduced line clearance time due to simplified assembly and a significant reduction in waste and quality issues. The developed novel thermoforming system and configuration is currently being applied to a second medication product line, leading to further predicted significant efficiency, waste reduction and maintenance gains and a projected additional 110,000 organ transplant medication capsule packs produced per year.