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Ordinal Logistic Regression Model of Failure Mode and Effects Analysis (FMEA) in Pharmaceutical Tabletting Tools

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ABSTRACT

The main objective of this paper is to use Ordinal Logistic Regression Modeling (OLRM) to predict and to investigate the relationship(s) between the different types of failures encountered in tableting tools of pharmaceutical industry and relevant tablet- and punch attributes. This would help minimize the occurrence of such failures in and avoid potential failure occurrences in future punch designs. Three punch attributes (punch diameter, location and shape) and five product attributes (tablet mass (gm), hardness (Kp), thickness (mm), moisture content (percent loss on drying (LOD %)) and sieve size (mm)) have been investigated in terms of their relative contributions towards different failure types. The present OLRM model has been successfully applied to the predict failure types according to the aforementioned factors. Furthermore, OLRM quantitatively links and evaluates the effects and contribution of each of these factors to the occurrence of different failure types. The OLRM methodology has been validated conveniently and proved to be powerful prediction tool. This is indicated by the marginal 2.4% error percentage encountered.

1. Introduction

In pharmaceutical industries, tablets are usually prepared by the instantaneous compression of powders between a two-punch set in a cylindrical die Fig. 1. The compression force may be supplied by either the lower or upper punch. Tablets are becoming complex and exotic in both shape and profile for brand identity marketing. As the tablets become more complex so does the tooling. Therefore, tooling strength and durability is a major consideration when designing a tablet.

The complex design and function of tableting allows a limited number of tool materials; particularly steel, to be used for this purpose among the many steels available. Compaction of granules into a solid form (tablet), with sufficient hardness and bond strength, results in high forces on the tooling, not just static loading but cyclic loading inflicting both stresses and strains. Pharmaceutical tabletting tools facing various types of tool breakage/failure; these include punch-tip breakage/chipping, tip wear, punch distortion and shorter punch-lengths among others.

In this research, it is wanted to investigate the types of failures encountered in pharmaceutical tabletting punch sets and what root causes are involved in these failures using Failure Mode and Effects Analysis (FMEA). This is expected to help in choosing the right tool material, tablet profiles as well as appropriate operating and maintenance procedures to reduce and/or eliminate punch failures.

Pharmaceutical tablets are solid, flat or biconvex dishes prepared by compressing a drugs or a mixture of drugs, with or without diluents. They vary in shape and differ greatly in size and weight, depending on the amount of medicinal substances and the intended mode of administration. It is the most popular dosage form accounting for 70% of the total produced med-

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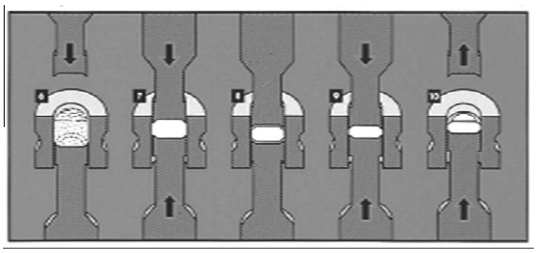

Fig. 1. A schematic illustration of a tableting compression station [2].

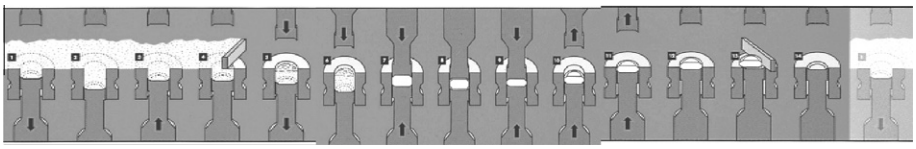

Fig. 2. A schematic illustration of typical production sequence of medical tablets; filling, compression and then ejection stage [2].

icaments. All medicaments are available in the tablet form except where it is difficult to formulate [1]. A tablet should have; elegant product identity while free of defects like chips, cracks, discoloration, and contamination, sufficient strength to withstand mechanical shock during its production packaging, shipping and dispensing, chemical and physical stability to maintain its physical attributes over time, the ability to release medicinal agents in a predictable and reproducible manner, and finally should have a chemical stability over time so as not to allow alteration of the medicinal agents [1].

Typical production sequence of medical tablets, Fig. 2, includes a filling stage, a compression stage and ejection stage. In the filling stage the exact measurement is used to give accurate weight and dosage for the tablet while filling the bore of the die with granules.

Compressing of granule is essential to provide the correct hardness and solidarity of the tablets. If a tablet is not compressed properly it can crumble. Normally a pre-compression is used prior to the main compression stage, the purpose of which is to remove excess air before the powder is fully compressed and the correct final pressure is reached. After compression an ejection mechanism lifts both lower and upper punches and ejects tablets into a collection tray and the entire cycle is repeated for each tablet.

2. Types and geometries of tabletting tools

As pointed to above, two punches are normally employed; an upper punch component to put the pressure on the powder and to control penetration depth into the die and a lower punch which components for die overfill and achieve final tablet weight, Fig. 3, [3]. The most important dimension of the tooling is the working length within a set of punches. Working length, Fig. 3, is normally subject to very tight dimensional control (0.002–0.005 in.) [3]. Variations in this specification will result in weight, thickness and hardness variation.

Different punch shapes depend on types of tablets as shown in Fig. 4. Punch shapes can be classified into: Round, Capsule-shape, oval, geometric (such as square, rectangular and triangular) and irregular shape punch which are used produce tablets with different shapes like fruits, animals, vehicles etc.

A proper tablet-shape selection is a key requirement for extended punch and die life. This, of course, has a great economical implications on the whole pharmaceutical sector.

Dies are basically hollow cylindrical parts, as shown in Fig. 5, within which the compression of powder between upper and lower punches takes place. Good tablet design is essential to prevent downstream production problems, consequently producing high quality tablets with maximum efficiency of the tableting process.

3. Failure Mode and Effects Analysis (FMEA)

FMEA is a procedure that is performed to classify each potential failure effect according to its severity and probability of occurrence. It is a systematic, proactive method for evaluating a process to identify where and how a part might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. Several research efforts had been undertaken for the analysis of defects in manufacturing tools by many approaches but mainly using FMEA [4].

In an attempt to increase die-set life, Alpagut et al. [5] investigated the possible use of Zirconia as a material for the manufacture of punches and dies for use in tableting machines and its effect on ejection of tablets. An experimental study to