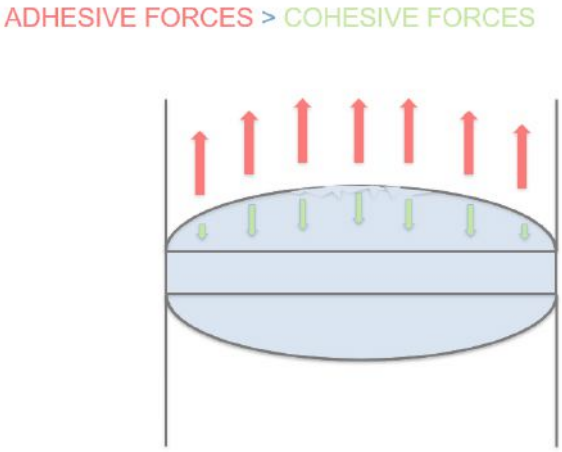
Understanding and Managing Tablet Weight Variation in Solid Dose Manufacturing

Tablet weight variation refers to inconsistent tablet weight or mass across samples taken from a single production batch. It is one of the most important quality control parameters in pharmaceutical manufacturing, as it directly ensures that each tablet contains the correct dosage of active pharmaceutical ingredients. Regulators such as the MHRA, EMA and the FDA require manufacturers to demonstrate that weight variation is within defined limits, typically assessed by accurately weighing a sample of tablets from each batch at regular intervals during production. Failure to control weight variation can lead to underdosed or overdosed tablets, presenting safety risks for patients and causing compliance issues for manufacturers, including the risk of needing to recall products.

There are several common causes of tablet weight variation and addressing them requires both technical expertise and robust maintenance practices. One of the most frequent contributors to weight inconsistency is excessive variation in the working lengths of punches. When punch working lengths are non-uniform, the volume of granule compressed in each die cavity can vary, leading to tablets with different weights. To avoid this, manufacturers should validate the working length of all new or unused punches before use. Additionally, the working lengths of used tooling should be measured regularly, and any punch found to be outside the acceptable tolerance range should be reworked or replaced. A solid maintenance process that includes rigorous assessment of tools offers reliable and repeatable procedures for length measurement and punch maintenance.

Another significant cause of weight variation is sticking or picking, which occurs when granule adhere to the punch faces during compression. This can cause material build-up, resulting in punches with effectively longer working lengths on some stations than others. This randomness leads to weight variation across the batch. To correct this, punches should be thoroughly cleaned and polished to remove product residue. Polishing the punch faces a higher-quality finish can also reduce the tendency for sticking. Increasing the amount of lubricant in the granulation can further improve material flow and minimise adhesion. Additionally, compression force can be increased within the safe operational limits of the punch tips to ensure complete formation of tablets. To address this cause of sticking, a specialist anti-sticking coating should

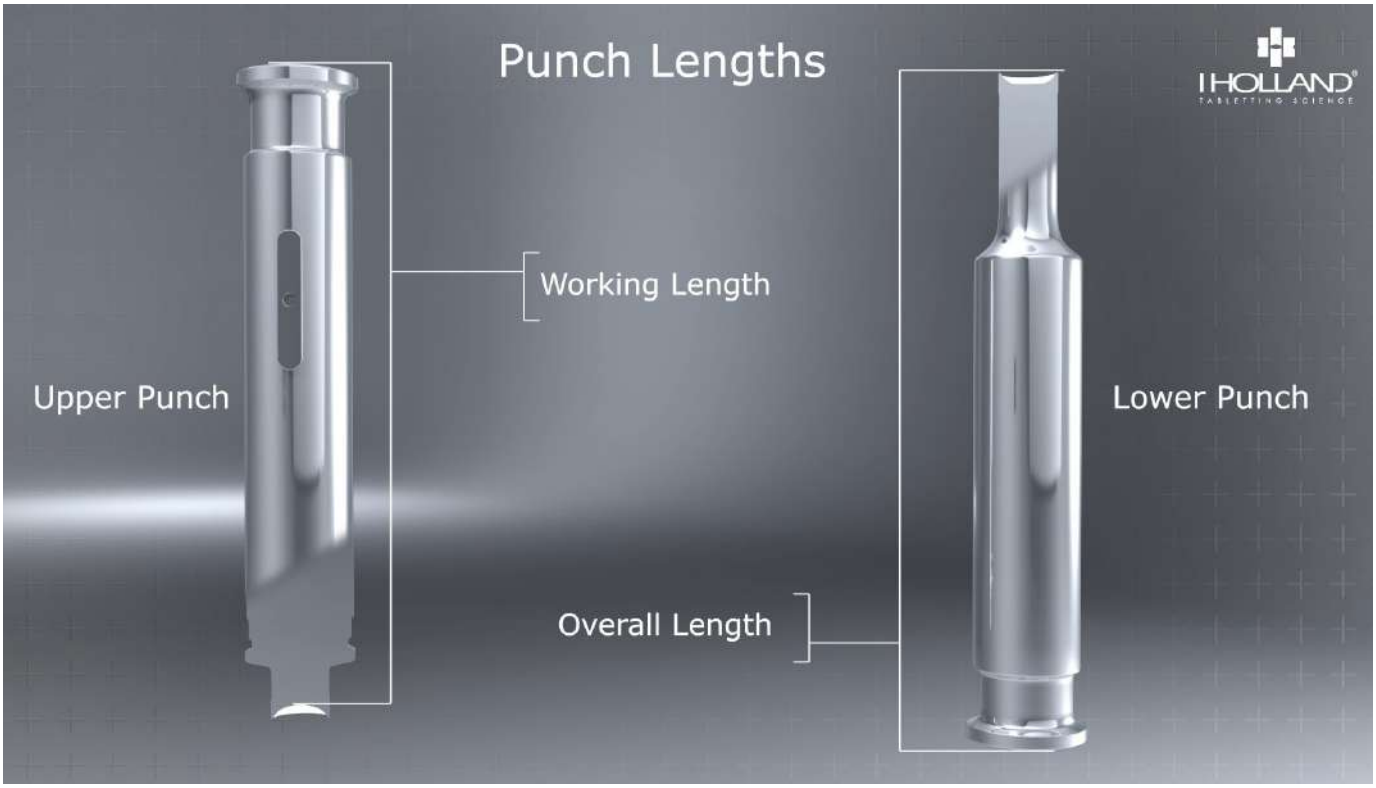


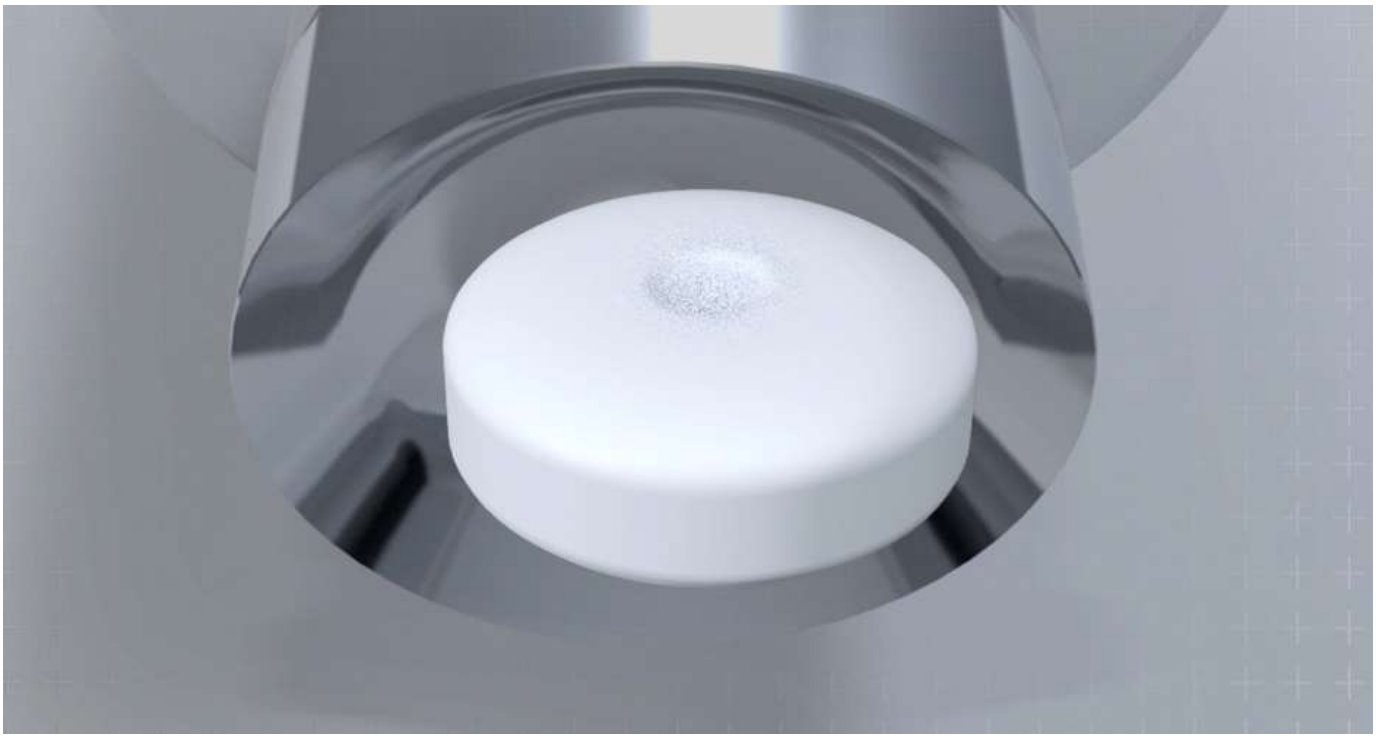
be considered. Choosing the correct tool coating can be overwhelming as there are many available choices in the market. This choice can however be supported by TSAR Predict™, a predictive model which helps identify the most suitable coating solution based on single particle adhesion force for the formulation. Modifying the tablet design may also help to achieve more uniform density and reduce surface defects contributing to sticking. A good tablet-tooling supplier will also be able to carry out compaction studies to identify solutions for sticking should a more detailed study of the issue be required.

A practical example of successfully addressing weight variation and sticking issues comes from a real case involving a customer producing effervescent tablets. The manufacturer was compressing a cleaning product into a 20mm round tablet using D Type tooling. The formulation, which acted as a degreaser, was not only highly corrosive but also prone to severe sticking, leading to progressive corrosion of the tooling. These issues were causing repeated production delays, increased maintenance requirements, and inconsistent tablet weights, ultimately affecting overall manufacturing efficiency and quality.

After consultation, the customer adopted a tooling solution featuring polymer inserts matched with a suitable grade of corrosion-resistant steel. These inserts, which can be made from materials such as Vulcalon, Adiprene, or PTFE, depending on the formulation characteristics, are designed to match the punch tip profile and are particularly effective in reducing product adhesion. Available in thicknesses ranging from 1.5 to 2.0mm, polymer inserts proved to be a cost-effective and easily replaceable solution that resolved the sticking problem without requiring a complete tool redesign. It is important to note that polymer inserts are only suitable for flat beveled edge and flat faced punch types. With the sticking issue resolved, the manufacturer observed a complete elimination of weight variation problems in their effervescent tablet production.

Inconsistent die filling is another major cause of tablet weight variation and is often the result of incorrect press set-up, poor operational conditions or poor granule flow characteristics. One aspect to check is the free movement of lower punches in their guides. If punches do not move smoothly, this can affect the consistency of die fill. Adequate lubrication is necessary to ensure proper motion, and the dust seals should be inspected for wear or damage. Punch brakes





must also be adjusted carefully. If they are overtightened, they can restrict punch movement and contribute to erratic lower punch behaviour, which in turn affects fill volume. Formulation buildup within the die bore could also lead to travel problems for the lower punch. Additional features can be added to the lower (a Bakelite relief), as well as ensuring correct clearances to help prevent the risk of this occurring.

Granule loss or gain after the die has been filled can also lead to inconsistent tablet weights. This is often due to excessive vacuum pressure or incorrect positioning of the vacuum nozzle, which can unintentionally remove or fail to remove excess powder. To address this, the vacuum settings and nozzle alignment should be checked and adjusted as needed. Ensuring effective granule re-circulation is also essential to maintain a stable and uniform supply of material to the dies throughout production.

When die cavities are not filling properly, further investigation of the feeder system is required. Problems can result from the feeder paddles, either due to incorrect speed or unsuitable paddle design. A blockage or starvation of the feeder system can also affect fill levels. Reducing the press speed can improve die fill by allowing more time for granules to flow. Another option on many modern presses is an independent speed control of the feeder paddles. Additionally, using the correct fill cam for the specific formulation and press setup can significantly enhance filling consistency and accuracy.

In conclusion, tablet weight variation is a complex but manageable issue in pharmaceutical manufacturing. It requires an integrated approach that includes precise tooling control, ongoing maintenance, and careful adjustment of press operation parameters. Regular measurement and maintenance of punch working lengths, elimination of sticking through suitable tooling material selection, cleaning and polishing, and optimisation of granule flow and die filling are all essential practices. Case studies such as the effervescent tablet example demonstrate how tailored solutions, developed through expert consultation, can directly resolve long-standing production challenges. By following proven methodologies, employing thorough and regular maintenance procedures, and drawing on specialist tools like TSAR~Predict™ and polymer insert technologies, manufacturers can achieve consistent tablet quality, meet regulatory expectations, and ensure safe, effective products for end users.

Rob Blanchard

Since joining I Holland in 2004 Rob has been instrumental in the development of I Holland's PharmaCote® range of surface treatments and coatings for tablet compression tooling designed to improve properties such as wear resistance, corrosion resistance and antistick characteristics. He was also part of the Eurostandard steering committee and responsible for I Holland's registration to ISO 9001:2015. Rob holds multiple patents linked to solid dose manufacture. Rob also co-ordinates I Holland's close collaboration with various respected academic research bodies.