Vision Inspection in Solid Oral Drug Manufacturing: A Game of Precision.

ACCURA™
PHARMAQUIP

Executive Summary

The pharmaceutical industry faces critical challenges in ensuring quality control of oral dosage drugs, where even small physical defects can pose serious risks to patient safety and lead to costly recalls. Traditional manual inspection methods have proven inadequate, leading to the development of automated vision inspection systems.

Current market solutions include high-throughput inspection machines capable of processing up to 600,000 pills per hour, but these systems often face limitations such as shape-specific change parts and high costs.

This whitepaper gives an overview of three machines developed by Accura Pharmaquip that offer a comprehensive solution addressing these challenges through three products:

1. Netra VS6: A 6-camera vision system inspecting 100 microns of each tablet within milliseconds, with a throughput of 100,000 tablets per hour.
2. Brahmi Series: An advanced system capable of inspecting both tablets and capsules, featuring a user-friendly 21" graphical interface and 6-camera vision system inspecting 50 microns of each product.
3. Brahmi Duo: A dual-line version of the Brahmi system, doubling inspection capacity while maintaining the same quality standards.

This technological advancement represents a significant improvement over traditional manual inspection methods, offering enhanced accuracy, efficiency, and compliance while maintaining cost-effectiveness and compact design.

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Introduction

Chemical defects in pharmaceutical tablets and capsules can lead to various physical defects, impacting product quality and safety. Common issues include cracks, breaks, size/shape variations, and internal structural defects (Abhinaya et al., 2019; Prajwala, 2018; Yost et al., 2019). Implementing robust quality assurance systems and leveraging these advanced detection methods can help pharmaceutical companies minimize defects and reduce the risk of product recalls (Abhinaya et al., 2019). When drug products are known to have potentially harmful effect on users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information's are reported to the drug office (FDA, 2016)

Manual Inspection has been done for many years before automation entered the game, but it comes with a lack of electronic reports, lots of room for error and inefficiency. Naturally, automated vision inspection becomes essential in the new age of technology (Bukovec et al., 2007).

The effects of Physical Defects

Effects on Patient Safety

Physical defects in drug manufacturing can significantly impact patient safety and pose potential health risks. Studies have identified various quality issues in solid dosage forms, including critical and major defects that could lead to product recalls (Abhinaya et al., 2019; Katta et al., 2020).

These defects may result from manufacturing process failures, inadequate quality control, or knowledge limitations (Obaid & Ali, 2018). The absence of essential drugs due to quality defects can have severe consequences for patients (Obaid & Ali, 2018). To mitigate these risks, pharmaceutical companies must implement robust quality assurance systems, adhere to Good Manufacturing Practices, and maintain a strong commitment to quality at all levels of production (Abhinaya et al., 2019; Katta et al., 2020). Defective tablets can result in financial burdens for manufacturers and potentially compromise patient safety. To mitigate these issues, pharmaceutical companies should implement robust quality assurance processes, provide effective staff training, and conduct thorough in-process quality checks before releasing products to market (A. N. et al., 2023).

Financial effects on Pharma Company and sector.

There are direct and indirect risks financially to the drug manufacturer and even its competitors if faulty drugs are shipped to patient. Direct risks to the drug manufacturer are the product recall prices it has to pay, the legal litigations it might have to go through and indirect could be lack in customer loyalty, customer trust and belief. Customer's lack in trust can affect the entire sector of the pharma market. It can cause stocks to crash and the economy to be directly affected. There can be operational halts and the following setbacks in product development and research. recalls (Abhinaya et al., 2019)

- Becton Dickinson (BDX) experienced a 0.9% decline in share price following a Class-I recall announcement, despite the overall industry gaining around 1.7% during the same period. This reflects investor concerns over recall-related risks and liabilities. [9]
- Similarly, Bausch + Lomb shares dropped significantly in intraday trading after announcing a voluntary recall of implantable eye lenses [10]
- Generic drug recalls can disproportionately affect certain brands. CVS's branded drugs were recalled about twice as often as their main competitor Walgreens, highlighting supply chain and manufacturing risks that could result in repeated financial losses due to recalls
- The recall of drugs like Pfizer's Oxbryta due to safety concerns can lead to both direct costs (withdrawal, legal, manufacturing) and indirect losses (market share, reputation) that can run into tens or hundreds of millions of dollars globally. [12]

It is important that large scale and short scale drug manufacturing companies adopt inspection measures in their operations.

What is Vision Inspection?

Vision inspection is an automated process using machine vision systems and image processing techniques to detect defects and ensure quality in manufacturing (Balaji, 2016). It makes the use of vision sensor cameras that use machine learning to register the characteristics of ideal product and then compare it with batches of those products to reject defective ones.

Types of Defects

Img 1: Types of defects

- **Capping**: Partial or complete separation of the tablet's top or bottom due to air entrapment.
- **Lamination**: Separation of the tablet into layers, also caused by air entrapment.
- **Cracking**: Occurs when deep concave punches cause rapid expansion of the tablets.
- **Chipping**: Happens when granules are too dry.
- **Sticking**: Granulation material sticks to the die wall.
- **Picking**: Material from the tablet surface adheres to the punch face.
- **Binding**: Caused by excessive binder or wet granules
- **Mottling**: Caused by coloured drugs, improper mixing, dirt, or oily lubricant.
- **Double Impression**: Caused by free rotation of punches with engravings.(Rana et Al, 2013)

What are the options in the market?

In the past years many developments have taken place in visual inspection in pharma. Formidable Pill Inspection machines of throughputs of upto 6,00,000 pills/hr have been developed by companies like Enclony's Planet series [13] , Sensum's SPINE [14], Viswill's T/CVIS-NS-V2 [15], Proditec's Visitab [16] series and the list keeps increasing. But the market faces limitations in some areas like- shape specific changeparts, which require support from machine manufacturer during newer product inputs, High prices due to larger number of cameras, larger sized machine bodies.

What is Accura offering?

Three automated systems

Accura aims at creating elegant design. Accura offers simple design that is cost effective, compact in size, without compromising on performance. Accura has three models starting with the Netra VS6, the Brahmi, and the double line version of that, as the Brahmi Duo.

Global Conformity and Compliance

Build

Accura's inspection machines are built to conform to global regulations in pharmaceutical industry, and last long. The body and all the non contact parts are made of S,S, 304 (heat resistant, corrosion-resistant and suitable to industrial environments), with product contact parts in S.S. 316 / FDA approved food grade material.

21 CFR Part 11

FDA's 21 CFR Part 11 requires electronic records and signatures to be trustworthy, secure, and traceable by enforcing system validation, audit trails, secure access controls, unique electronic signatures, and data integrity measures**.** Compliance ensures accuracy, reliability, and FDA inspection readiness for electronic systems used in regulated industries. Accura's machines are compliant with the FDA's 21 CFR part 11. [1]

Netra VS6

The 6 vision Camera System

Using 6 industrial vision cameras capable of inspecting 100 microns of each tablet within milliseconds, Netra has a throughput of 1,00,000 tablets/ hour. The use of Servo systems control precise focal lengths for tablets of all sizes. The vision system is capable of inspecting over 8 different types of defects.

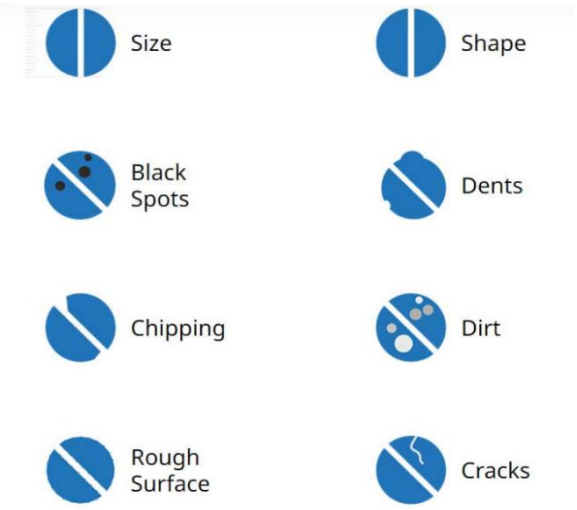
Img 2: Netra VS6 Camera setup

Efficiently designed change parts

The change part is a product-specific requirement. The selection depends on the width or the diameter of the product. It is simple to replace- without the use of tools- with the use of four knobs.

Operations

As shown in image 2, the product moves through Conveyor 1, each tablet is inspected by five cameras (C1-C5) placed precisely to capture its image from the top (C1) and from four lateral angles (C2-C5). Any tablet that fails this inspection is pneumatically discarded through the first rejection point (R1) into an internally provided rejection bin.



Img 3: Pill defects that Netra inspects

The filtered tablet stream now travels along Conveyor 2, where the vacuum-pull reverses, and the underside of the tablet is inspected by the bottom camera (C6). Any defective product at this stage is rejected through the second rejection point (R2) into the internally provided rejection bin.

The flawless product stream is collected in a separate bin at the discharge end of the machine.

The Brahmi Series

New Ground Covered- Capsule Inspection

Unlike Netra, the birthgiver to automation in Accura, Brahmi develops into inspecting tablets AND soft/hard gel capsules. Provided with a user-friendly 21" graphical interface for teaching and simplified operation.

Functioning as a highly efficient and meticulous system, Brahmi ensures a comprehensive examination of tablets and capsules, addressing an extensive range of variations and cosmetic defects.This includes scrutiny for size, shape, stains, spots, embossing, debossing, and printing irregularities, thereby guaranteeing the highest quality pharmaceutical products

Compact and Robust Design

Brahmi's size is compactly designed to suit and fit the majority of pharma plants. The compactness in size is designed without compromising in build quality and strength.

The 6 Camera Vision system

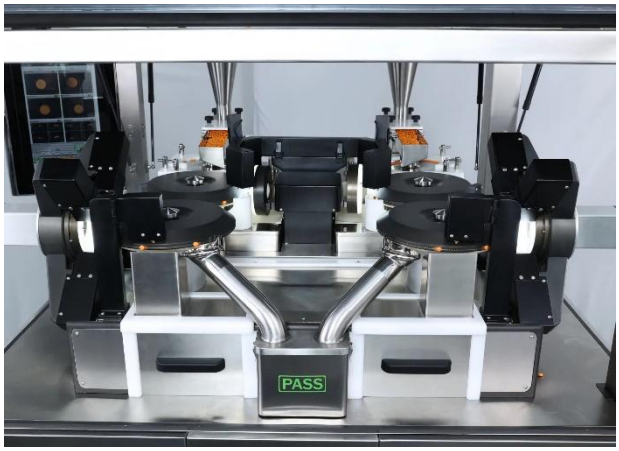
Brahmi's vision system, is capable of inspecting 1,50,00 product per hour. Equipped with a sophisticated 6 camera system, Brahmi meticulously inspects every 50 microns of each tablet, creating a comprehensive 360 degree view in milliseconds. Notable features of the Brahmi vision system include:

- Well-managed cabling for Connection Integrity
- Inbuilt high-intensity light source for optimal illumination
- 6 industrial vision cameras with 6 independent image processing controllers
- High Resolution depth in each Camera.

The Brahmi Duo

The Brahmi Duo is the same technology and design as the Brahmi operated on two simultaneous lines, for higher throughput. The Brahmi Duo, is capable of all that the Brahmi is but at a Double inspection yield.

The Brahmi Duo inspects upto 3,00,000 product per hour depending on size.



Conclusion

Physical defects in pharmaceutical tablets and capsules pose significant risks to patient safety and contribute to costly product recalls and reputational damage for manufacturers. While manual inspection methods have historically played a role in quality control, they are increasingly inadequate in meeting the accuracy, efficiency, and traceability requirements of modern pharmaceutical production.

Automated vision inspection systems offer a viable solution to these challenges. Accura's inspection technologies—Netra VS6, Brahmi, and Brahmi Duo—demonstrate how compact, high-throughput systems can be integrated into manufacturing processes to detect a wide range of defects with high precision. These systems are designed to meet global regulatory standards, including FDA's 21 CFR Part 11, ensuring both compliance and reliability.

As the industry continues to move toward automation, such systems represent an important advancement in improving product quality, reducing human error, and maintaining the integrity of pharmaceutical supply chains.

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