Machine Vision based Quality Control: Importance in Pharmaceutical Industry

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ABSTRACT
Quality is important for customer satisfaction and sale of product in the competitive market. Present day consumers have wide variety of demands and needs leading to increased complexity in variety of products. The price war, high quality, traceability, necessity of disclosure of quality, the norms and regulations, imposes the manufacturers to have flexible design with zero defects in a highly competitive market. To achieve the high quality that is demanded by the customers, manufacturers and their suppliers must rely on Machine Vision to prevent defects at multiple stages of production. Machine Vision has become an essential part of pharmaceutical industry, due to the regulations and the health impacts. This paper presents basic concepts of Machine Vision with examples of quality control and production assistance in manufacturing and packaging of pharmaceutical products.

Keywords
Machine Vision,Mathematical Morphology, Image Processing, Inspection, Quality Control, Traceability, Tablet inspection, Blister inspection, Print inspection, Packaging, Traceability.

1 INTRODUCTION
One of the main industries in India growing at high rate is pharmaceutical. Unlike other countries, the Indian production is for local Indian consumption and also for the exports. Until recently, the Indian local consumption is more, but, the scenario has changed and the exports have become an important part of production. This change imposed the manufacturers to use 100% quality control before exporting the products, which has triggered the usage of Machine Vision systems for high quality products. In addition to this, the norms and regulations were developed to produce the reliable products and this process can be achieved using Machine Vision [1][2][3].

1.1 Pharmaceutical Industry
The Pharmaceutical industry in India is the world's third-largest in terms of volume and stands 14th in terms of value [4][5]. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between 2008 and September 2009 was US$21.04 billion While the domestic market was worth US$12.26 billion. Sale of all types of medicines in the country is expected to reach around US$19.22 billion by 2012. The Indian pharmaceutical market is expected to touch US$ 74 billion sales by 2020.India have every chance to capitalize the opportunity to become a pharmaceutical Superpower in 2020 and a hub for all pharmaceutical manufacturing & research needs. The growth of the Indian over-the-counter or OTC market (that is advertised non-prescription medicines) has outperformed globally. It has been observed that the global OTC market over the past eight years has grown rapidly and is expected to continue. Currently, India ranks 11th in terms of the OTC market size globally.

Following regulations in Pharmaceutical industry is very important due to their high risk on health. These regulations also different and depending on the type of medicine and the country where it will be used [6]. Due to this, there is a need for highly flexible, configurable system that verifies the quality and the required regulatory rules. The Machine vision system is used for tablet quality, conformity to norms and without mix with other tablets [7]; Blister packaging while checking the missing, broken tablets and without foreign particles, tablets; traceability [8] by printing and verifying coded information like barcode, data matrix, pharma code, batch number, manufacturing date, validity date; Verification of packaging like properly closed, required material like information sheet is inserted, required information is printed on the box (Fig. 1).

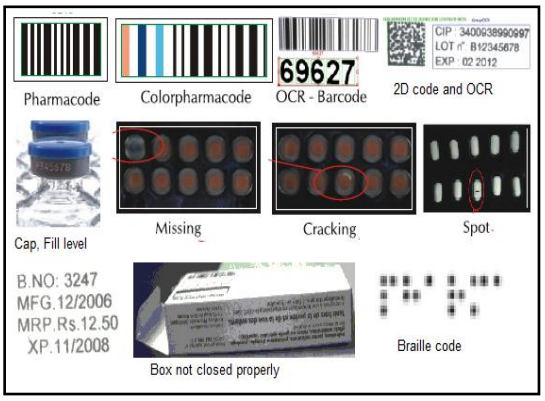

Fig. 1: Different Machine Vision applications in Pharmaceutical industry

1.2 General
The advantage of the Machine Vision system is to quality control, regulation verification and also updates the stock and Management Information system for statistical analysis, decision making and select best suppliers. Following the negative press about product recalls and rejection, the industry aggressively pursues a 100% product inspection and tracking policy using machine vision.

These concepts are explained in the section 2 on "Machine Vision". The real life examples of such Machine Vision systems are explained in detail in the section 3 on "Applications". The applications developed by the author which are in the pharmaceutical industry explained in the sub sections.

2. CONCEPTS OF MACHINE VISION

The terms, Digital image processing (DIP), Computer Vision (CV) are more frequently heard and millions of publications are available. But Machine Vision is more than DIP and CV, which includes a complete practical solution starting from acquiring an image to interacting to MIS. The DIP and CV resolves the problem from an existing digital image. But, Machine Vision includes all integration with external production systems, camera, lens, lighting, the conveyor belt to move parts and after processing the image, to ejectors to sort the products, update the Management Information system. Hence, the Machine Vision system (Fig.2) is normally done by a team of members with expertise in acquisition of image, mechanical, electronic, electrical and Management information systems.

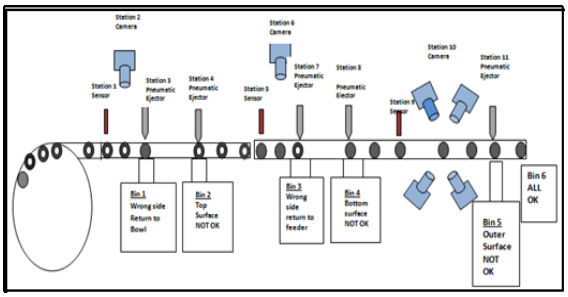

Fig.2: Example of a Machine Vision System with Camera, Lens, Lighting, Belt, ejectors, Sensors.

2.1 Acquisition

Camera is the major part of the vision system by which, the image is acquired, lens and lighting help camera to have a good quality image. The main component of the camera is the sensor which converts the light reflected from an object is digitises and forms an image. The sensors are categorized as CCD, CMOS and the functionality like resolution, grey, colour, intensity, line scan, area scan. Simple cameras capture images and transfer to a computer for further processing via different interfaces (USB, Giga Bit). Smart cameras (Fig. 3 b) can acquire images, does processing using DSP and send signals to external systems.

Lens or optical system in a machine vision system is used to collect the light rays and transmit into the image sensor in the camera [9]. The factors must take in to account to determine the correct lens for a particular application are: Focal length (the distance between principal plane and the focal point), Mount (an interface between the camera and lens: C, CS, S, F and M42), Aperture (the amount of light let to pass into the lens), Depth of field (the range of the lens to object distance over which the image will be in sharp focus).

Lighting is the base of machine vision system and is the information carrier, whatever information the camera receives, it is from lighting [10]. It is believed that two-third of robustness in machine vision solution is lighting. The illumination determines the quality of the features to be extracted from the image. The features need to be presented with a maximum of contrast. The challenge of illumination is to increase the signal to noise ratio, and expose these features to maximize the contrast. Any effort invested in illumination will increase the system's inspection performance, repeatability and reliability; it will also decrease the complexity of the software. Common light sources used are LED's, Fluorescent tubes, halogen source (for colour inspection). The placement of illumination with respect to component and camera also plays a vital role in acquiring a better image. Some important illuminations used in machine vision system are: Back illumination, Front illumination, Oblique illumination, Dark field illumination, Coaxial illumination and Dome light.

The quality of an acquired image of a machine vision system consists of a camera, lens and lighting.

2.2 Processing

Image is an N-dimensional matrix and needs to be processed to extract information. The processing is done for adjusting the image (geometric correction, shading correction, calibration); Noise removal (integration, contrast enhancement, Mathematical morphological filters); Segmentation (threshold, region growing), processing (removal of unwanted, separate touched objects); Feature extraction (blob analysis, Hough, FFT); Classification (Feature analysis, Neural networks, Principal Component Analysis).

Three major types of techniques used (a) Mathematical Morphology [11][12][13][14]; (b) Digital image processing and analysis [15][16]; (c) Machine Learning [17]. These algorithms were already programmed and available in both open source software like OpenCV[18] and also commercial software like MATLAB [19][16] and LabVIEW [20]. A combination of the above was used in the applications presented in the following sections. The add on library was developed based on the existing software to resolve the applications explained in this paper. Some of the applications needs 3-D images and 3-D image processing optimised algorithms [21][22]][23], that are used in pick and place, Braille reading applications in pharmaceutical industry.

2.3 Interfaces to External Systems

Machine vision system involves various disciplines, from optical engineering to mechanical engineering, from electrical engineering to software. Vision is the brain of any machine vision system; nevertheless automation is the heart of it. Due to mass production of component in any production or manufacturing organization, inspection system has to cope with the production rate. This is possible only through automating the inspection system. Many machine vision systems involve conveyor belt or indexing table to convey the parts and bring it before the vision system for inspection. The cameras and the lighting are mounted over the conveyor belt. A sensor is used to trigger the camera for capturing the image just as the component arrives in the field of view of the camera. It can be of proximity sensors (capacitive or inductive) or photoelectric type. In order to dispense the components after inspection to the appropriate collection bins, ejection system is used. The ejection system can be pneumatic where the gush of air or pneumatically actuated cylinder is used to push the faulty components out of the conveyor belt. Electrical actuators like wiper can be placed over the belt to divert the faulty components from the course of travel.

Fig. 3: (a) Vibratory Bowl (b) Intelligent camera with Lens and Lighting

Other aspect involved in inspection is the orientation of parts. Sometimes the part has to be oriented to suitable angle and brought before the vision system. This is generally done through vibratory bowls (Fig. 3a). The parts are dumped in the vibratory bowls; the vibration produced in the bowl makes the part come out one by one and with desired orientation. This is then directed to the conveyor belt.

Other aspect in the automation system is the electrical interfaces. The vision system has to communicate with the automation system. The control of automation and the decision signals generated from the image processing algorithms have to be suitably controlled and tapped. In today's automation world one such common device is the PLC. The signals from automation system to vision system and vice versa can be routed through this I/O device. PLC also supports PROFIBUS for data transfer and of course Ethernet interface is also emerging at a quite faster rate.

2.3 Interfaces to Management Information System (MIS)

Management information system (MIS) is used to analyze and facilitate strategic operational activities and to make decisions. The information about the quality, production status and the performance of the products manufactured in the company helps highly to satisfy existing customers and also to capture new markets. Machine Vision can be interfaced to MIS and update the information about the inspection. This information in MIS can be used to make statistical analysis, reporting, supplier analysis, quality analysis, production system performance. This information can be utilised by decision makers to promote their products better, send information to customers for approval before delivery; repair, modify, upgrade the production system based on the inspection results. A generic interface was developed to integrate with enterprise resource planning (ERP), Knowledge management system (KMS), Customer relationship management (CRM), Supply chain management (SCM). This can easily be extended for other systems. This part of interface is specific to customer needs and customization is required.

3. APPLICATIONS

Machine Vision applications are for quality inspections that lead to driving towards a zero defect products. Manufacturers expect defect free products from suppliers and from production assembly line, so that the product recall liability costs will be reduced and customer satisfaction will be increased. Critical medicines must be zero defective because it may lead to health hazard to someone and hence must be inspected with 100% reliability. The second important application is the product traceability that can be used for stock maintenance, supplier quality and also for any customer requirement to find the origin of any defect. The tracking is done by reading label using barcode, data matrix and optical character recognition. The machine vision system can detect, validate the products at each stage of manufacturing, checks the correctness and indicate the production system failures. The Machine Vision system must be build with repeatability and accuracy, and resist to environments with heat, vibrations, dust, and humidity, interface to existing MIS and production system.

The multi-disciplinary development team needs expertise in cameras, sensors, lens, illumination, mechanical, electrical, electronics, robotics, MIS and project management. The machine vision applications that are critical, representative and developed by the author for the pharmaceutical industry are explained.

3.1 Pharmaceutical Applications

The medicines manufactured are used worldwide used by the patients of different languages and also by blind. It is critical to be 100% guaranteed that the medicine in the form of tablets, powder or liquid filled in are correctly inserted, the accurate information sheet is attached and the labels inscribed on the packet are correct, without which it could be danger to the life. Hence the Machine Vision has importance for ultimate product safety, traceability, process optimisation, 360º all round inspection, 100% quality control, process reliability around the clock. In addition to this, the regulation for different countries varies and is difficult for any manual inspection and a machine system is essential to follow automatically the regulations based on the destination.

The pharmaceutical industry produces several different product in varied format (Tablets of different size, shape; powder, liquid, etc) and the regulations varies based on product type (critical, OTC, etc), destination (the regulations to Europe could be different compared to Africa), it is important to have a flexible configurable Machine Vision system adopted to customer needs. The typical Machine vision system is shown in Fig. 4. The system is programmed for verification if the blisters are inserted correctly; if information leaflet is inserted; if the box is closed properly and then prints the necessary information on the box (datamatrix, lot number, date of manufacturing and date of validation). Also verifies the printed label for correctness. If any of the information is not validated, the corresponding carton will be rejected. Some of the applications that can be done using such a machine vision system are show on the top right side of the fig 4.

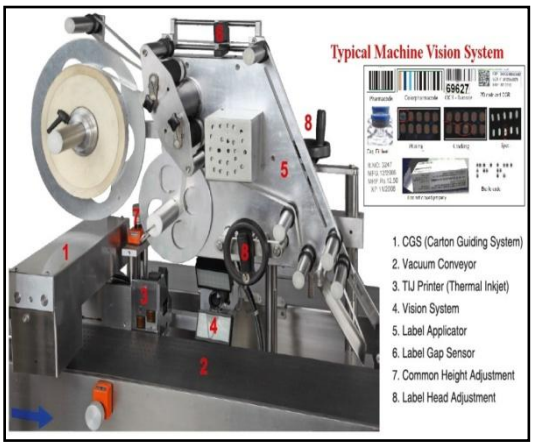

Fig. 4: Typical machine Vision system with packaging machine in Pharmaceutical industry

The tablets are produced, then inserted in to blisters, then the group of blisters along with the information leaflet inserted in to a pre-printed carton. The carton is closed and the label is printed. The Machine Vision system is used in each phase of the manufacturing, so that the effort at next level will not be wasted, if the product found defective at any stage. By validating at each stage by web inspection, the manufacturing equipment that producing defective products can be rectified immediately.The applications in pharmaceutical industry are lot in number and some of the very important applications are explained below with respective images.

Tablet Inspection and Sorting

The tablets manufactured either in factory or sometimes outsourced. The manufactured tablets need to be verified for conformity (outside) based on the combination of colors, diameter, lengths (Fig. 5a). Such Machine vision system (Fig. 5b) we generally will have two ejectors, one to rejected tablets and the other to place the validated tablet.

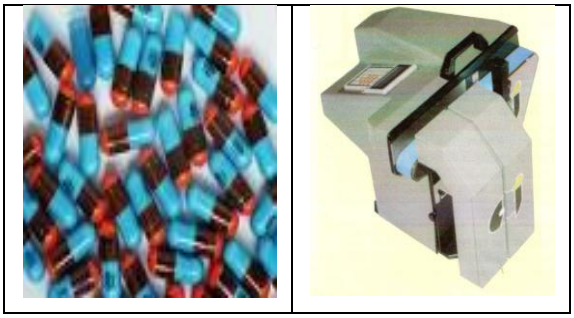

Fig. 5: (a) Tablets to sort based on size, color, shape (b) Configurable Sorting machine with 2 ejectors

Blister Inspection

The blisters are sheet with pockets to hold the tablets and shielded by cover, protecting the product against external factors such as humidity and contamination for extended periods of time. The tablets are placed in to the pockets of thee blister and covered by a transparent sheet. The machine vision system takes an image at this moment and verifies for: Alignment of tablets (Fig.6a) foreign particles (Fig 6b) over the tablets, broken tablets, non confirm tablets (Fig. 6b), missing tablets (Fig. 6c), The image is segmented to get each tablet as one blob and each such blob is analyzed for size, shape and color to validate the blister. On each blister the lot number and the expiry date are engraved and is very difficult to read them. Special light with homogeneous back light system is used to read the numbers using Optical character recognition system (OCR). The decoded numbers are validated against the database of the product (Fig. 6d).

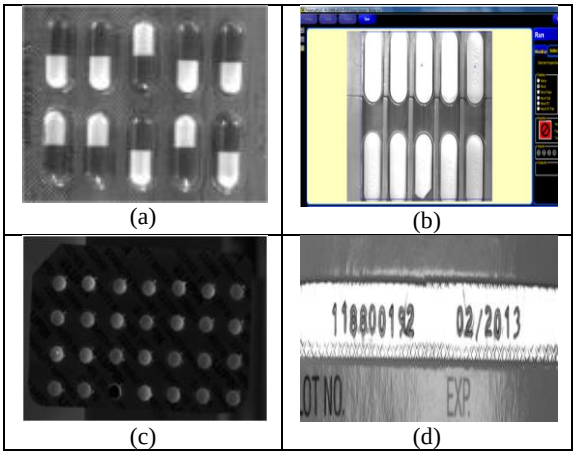

Fig. 6: (a) Tablets not aligned (b) Blister having foreign particles and also a different tablet (c) Missing tablet (d) Lot number and expire date.

Blisters and Leaflet Verification inside Carton

The carton is folded by the folding machine and the blisters are inserted. The number of blisters in a carton varies and configurable based on the product. The Machine Vision system does pattern matching technique to find if number of blisters is inserted correctly. If not validated, the carton will be ejected. After validation the leaflet is inserted and Machine Vision system validates using segmentation techniques, to make sure the correct leaflet is inserted (Fig. 7). After both successful validations, the carton is closed.

Fig 7: Leaflet inserted correctly (Top left); Blister missing and one Blister turnup side down (Top right) Leaflet inserted (Bottom left); Blisters correctly inserted, but leaflet missing (Bottom right)

Carton Packing

The validated carton is closed by the packing machine. On the closed side of the carton, the label (Datamatrix, lot number, expiry date) is printed that indicates the contents of the box. If the box is not closed properly, there is a possibility for blisters to come out or the printing may not be done correctly due to non-uniformity of surface. Intentionally, the background near the edge of the box as black (Fig. 8) and the segmented edge on folded side can be seen clearly and the angle of this edge indicate how the box is closed.

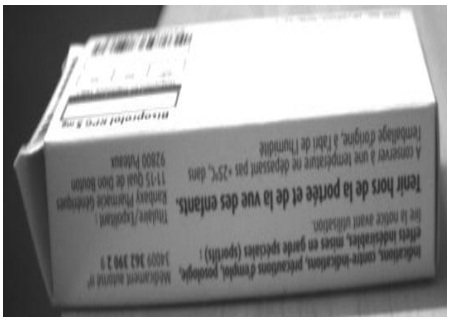

Fig. 8: Verify if both sides of the carton are properly closed (Here one side not closed)

Print Label Inspection

After the validation, the carton is sucked towards the printing unit, using vacuum and the label information is printed. This information varies based on the product contents and used for billing in shop; identifying the lot number for traceability; manufacturing and expiry dates. Hence it is very important that this information must be readable accurately. In Pharmaceutical, data matrix, code bar and data bar are most used codes as per the standard. The Machine Vision system decodes such bars and also calculates the grading parameters that help to decide on readability. The other information is decoded using OCR. The decoded information is then validated fusing the data from the database. The CIP number is not readable due to over ink (Fig.9 top left), the label is printed with a rotation due to problem in vacuum machine (Fig. 9, top right), the label printed correctly (Fig. 9, bottom left) and missing characters in label (Fig. 9, bottom right).

Fig. 9: Data Matrix decoder and OCR usage to test readability of label on carton

Update Management Information System (MIS)

One of the great advantage of Machine Vision system is that the up to date information about production quality in real time. As soon the product is manufactured, the MV system will do all above said validations and update MIS with the statistics of the quality. This information can be used (a) by the management to take the decisions (b) Sales and customer support personal to inform their customers with statistics (c) To modify the production system to prevent any defective product immediately.

4. CONCLUSION

Pharmaceutical products are critical due to their importance on human health and quality control is essential to supply reliable and safe medicine to their customers. Machine vision plays an important role to control the quality, assist in packaging, track the products used in case of problems. In addition to liability and public safety concerns, tracking also helps companies to better manage their suppliers. Track every barcode and store every image so they can build a visual history of defective products to improve their ability to identify and negotiate the problem with the suppliers. The key concepts along with applications to inspect, assist and track some important manufacturing phases of pharmaceutical industry. This publication helps to understand the importance of machine vision in manufacturing to sustain against lack of manual resources, increase in productivity, high quality and traceability.

5. ACKNOWLEDGMENTS

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6. REFERENCES

[1] Alexander Hornberg, Handbook of machine vision, Wiley-VCH, 2006

[2] PinnamaneniBhanu Prasad, "Machine Vision solutions: 100 Industrial application notes", To be published.

[3] Machine Vision Systems and Components market, Global analysis and Forecast (2013-2018), published by MarketsAndMarkets, SE1420, 2013.

[4] Pharmaceutical Packaging Market-Global Trends, Opportunities and Forecasts to 2017, published by MarketsAndMarkets, PH 1347, 2013.

[5] Overview of Indian Pharmaceutical Industry, published by Tata Strategic Management group, 2008.

[6] Quality assurance of pharmaceuticals, A compendium of guidelines and related materials, Volume 2, World Health Organization 2007.

[7] Peng Zhao and Shutao Li, Tablets Vision Inspection Approach Using Fourier Descriptors and Support Vector Machines, The 9th Int. Conference for Young Computer Scientists, IEEE Computer Society, pp.1743-1748, 2008.

[8] PinnamaneniBhanu Prasad, "Importance of Traceability in Pharmaceutical industry: Solutions", R&D Report, to be published.

[9] Greg Hollows and Stuart Singer, Matching Lenses and Sensors, Vision System Design, 2009.

[10] A Practical Guide to Machine Vision Lighting, Whitepaper, National Instruments, 2010.

[11] Jean Serra, "Image analysis and mathematical morphology", Academic Press, 1982.

[12] Bhanu Prasad P, Lecture Notes on "Mathematical Morphology and image analysis", Lecture notes for training, Steel Authority of India, Ranchi, 1984.

[13] Bhanu Prasad P, "Machine Vision Systems and Image Processing with Applications", "Journal of Innovation in Computer Science and Engineering", Volume 3, Issue 1, 2013.

[14] Bhanu Prasad P, C Lantuejoul, J.P.Jernot, J.L.Chermant, "Unbiased estimator of Euler-Poincare characteristic", ActaStereologica, 1989, Vol 8/2, PP. 101-106.

[15] Rafael C. Gonzalez, Digital Image Processing, Pearson Education India, 2009.

[16] Rafael C. Gonzalez, Richard Richard Eugene Woods, Steven L. Eddins, Digital Image Processing Using Matlab, Pearson Education India, 2004.

[17] Pham D.T, Bayro-Corrochano E.J., Neural Classifiers for automated visual inspection, Proc. Instn. Mech. Engrs, Vol. 208, 1994.

[18] Open CV: http://opencv.org/

[19] Matlab: http://www.mathworks.in/products/matlab/

[20] Labview image processing: http://www.ni.com/analysis/lvaddon_vision.htm

[21] Bhanu Prasad P, M. Coster, JL Chermant, C Lantuejoul, "Basic Mathematical Morphological tools for analysis of 3-D structures", Published in ActaStereologica, 1987, Vol.6, pp.773.

[22] Sujatha P, P. Bhanu Prasad, J.H.Johnson, J.L.Chermant, "Low level vision system for 3-dimensional image analysis", ActaStereologica, 1989, Vol 8/2, PP.569-574.

[23] Dhanya S Pankaj , Rama RaoNidamanuri and PinnamaneniBhanu Prasad, 3-D Imaging Techniques and Review of Products, Proceedings of International Conference on "Innovations in Computer Science and Engineering 2013".

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