

Identification of A Fake Medicine Packaging Print From its Dot Sizes and Shape

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Abstract- The pharmaceutical industries face great challenge for wide marketing of fake medicine. It is a huge threat to society also because of the critical health hazards due to the fake medicines. The easiest way to market the fake medicine is to copy and print the original medicine package by the counterfeiters. Hence in this study, it has been discussed how the dot sizes and shapes of color image prints can be used to identify the authenticity of the original package printed by the manufacturers or their authorized printers. The goal of this study is to authenticate the pharmaceutical package print from microscopic analysis of printed foil. The blister foil is chosen as the substrate because it has extensive usage in pharmaceutical packaging industry. Studies of the dot shapes at the microscopic scale may be taken as an intrinsic signature of printer. This work has been focused to differentiate between the original print and its scanned and reprinted (mentioned as reprint) samples, which simulates the standard practice of copying and reprinting by the counterfeiters. The differentiation is done on the basis of different parameters such as dot area, major and minor axis of dots, eccentricity of the observed dots. First a reference color chart IT 8.7/3 has been printed by three different gravure printers (P1, P2, P3). Then the images of the print samples (P1, P2, P3) are captured using calibrated camera and are printed again in those three printers, which are referred to as reprint (R1, R2, R3). The samples printed in the gravure process are analyzed using the Lays & Mayo microscope with 4x zoom and ScopeImage 9.0 microscope software. The parameters like dot area, major axis, minor axis and eccentricity of cyan, magenta and yellow (20 %, 40%, 50%) tint for print and reprint samples are taken by using MATLAB R2018a. For the detection purpose the canny edge detection algorithm has been applied on the microscopic images. Then the boundaries of the objects are being calculated by detecting the contours of the detected edge dots in the samples. From the results, it has been observed that the dot shape parameters (Dot area, Major and Minor axis, Eccentricity) may be used to distinguish the print sample from reprint sample.

Keywords- Medicine package printing; Anticounterfeiting, dot area; major axis; minor axis; eccentricity.

I. INTRODUCTION

In the last 30 years, printing technology has helped to fight against counterfeiting, a plea threatening citizen safety and impacting the financial health of pharmaceutical packaging industries. The authentication of the packaging is considered as an important step in the investigation of

suspected counterfeits of pharmaceutical products. Due to the advancement of printing technologies, the emergence of counterfeits with a better appearance may be observed. Printing forgery using the high-quality printers has been applied to reproduce the printed content of the original. In the recent years, due to the easy access of the high-quality printing technologies, the importance of package printing security has been increased to prevent the counterfeiting or forgery of pharmaceutical packaging, images. This study will help to identify the medicine package printing counterfeiting. In this study, the gravure printing process is used to print on the blister foil which is widely accepted as substrate in pharmaceutical packaging industry due to its inertness, impermeability and non-reactivity properties. Gravure printing is considered as major printing technology for the packaging industry. very little study has been done on the gravure printing process and its security issues. The most typical method of counterfeiting packages is to replicate the package's text and graphics and recreate them. One way of counterfeiting the actual product item is scanning or capturing it and then reprinting it. The original sample is being scanned and then reprinted using a variety of digital cameras, mobile cameras, scanners, and other devices. Das I et.al. has shown a promising solution based on a pattern recognition process to identify a print document (original) from a reprint document (copy or fake) [1,2]. This study has demonstrated that the geometrical shape of printed dots can be analyzed at microscopic scale to differentiate a print from a reprint, as a fingerprint.

II. BACKGROUND

Pharmaceutical package printing becomes very critical as the marketing of the product mainly depends on it. It becomes more critical for medicine packaging as counterfeiter can market fake medicine just by reprinting the package properly. It is a major threat to mankind. Beside this, the giant pharmaceutical companies are also facing problems as it not only affects their market but also affect their reputation. It necessitates the research work to differentiate the original medicine package print with the fake one. Joshi A. V. et al. [3] proposed a model to predict print flaws or empty area on film substrate for gravure printing, using an ANOVA and Regression model. Kundu P. et al. [4] have proposed a method to identify an original

print on blister foils with different gravure printing machines using the color gamut volume. The color gamut of the printed sample (original) and a scanned reprinted sample (fake) was analyzed to distinguish between them. Few papers worked on the authentication of printed blister foil samples using color values and ANN (Artificial Neural Network) model [5] and also differentiate between original and duplicate samples of blister foil print sample printed with gravure printing technique using spectral signatures, color differences [6]. Tkachenko I. et al. [7] developed a technique to identify blister foil packaging using a chemically etched, laser-engraved printing cylinder. The report [8] has mentioned about serialization-based product authentication, with a unique identifier (e.g., 2D barcode) which help to track and identify each medical package along the supply chain. However, the process is expensive and may be exposed to getting compromised by counterfeiters. Authentication of physical products such as documents, goods and drugs are generally done by using the stochastic structure of either the materials that composes the product or of a printed package associated to it. Authentication can be performed for example by recording the random patterns of the fiber of a paper [9]. In the recent years, due to the improvement and availability of the high-quality printing and scanning devices, the number of counterfeiting or forgery of documents and product packages is increasing. Therefore, the importance of various security elements has been proposed to prevent the, images [10, 11,12]. Each printed and scanned set of dots (a dot being a binary element) have been affected from a stochastic non-invertible noise which creates the difficulties during the reproduction of the original graphical code [13,14,15]. Furthermore, Nguyen et al. [16] have suggested a probabilistic model that consist of vector parameters describing a spatial interaction binary model with inhomogeneous Markov chain. This study has reported how those parameters have determined the location and described the diverse random structures of microscopic printed pattern. Q. Nguyen et al. [17] have performed a statistical analysis on microscopic printing to identify the authentic printer source using micro-tags consisting of patterns of microscopic printed dots in the paper. This study has employed multi-class Support Vector Machine (SVM) and Random Forest (RF) on five shape descriptor indexes of the micro-printing patterns. The use of intrinsic texture features of the packaging material is discussed by R. Schraml et al. [18]. This study has investigated the feasibility of a classification-based drug authentication system based on images of the cardboard packaging and top & bottom blister surface texture.

Much of the previous research has focused on the offset or digital prints. Limited study has been concerned about the security issues of gravure printing process. Moreover, most of the studies have been performed on papers. Few works have been conducted on the blister foil. As the blister foil is widely accepted as package substrate in the pharmaceutical industry, foil prints on, gravure are selected as the substrate of studies. This paper has developed an approach to identify the authentic prints using identifying parameters like Dot

area, Major and Minor axis, Eccentricity of microscopic printed dots in package prints. Development of authenticity of printed product from counterfeiting depends highly on the capacity to measure and control the properties of the print. With the advancement of modern digital measurement instruments, accurate measurement of printed dots at the micro-scale is becoming easy. The main objective of this study is to identify the reprint (simulated counterfeited/copy) from the print (original) based on the print parameters like-dot area, major and minor axis eccentricity of printed and reprinted dots from the samples. The reprint is produced from copying the original print with scanner or camera by the counterfeiter. The aim of this study to measure and identify the print parameters like-dot area, major and minor axis, eccentricity and to check how these parameters can be used to differentiate printed dots from scanned reprinted dots from the samples. If these parameters are carefully monitored, it may help to identify whether the print is original or it is copied and reprinted.

III. EXPERIMENTAL MATERIALS AND METHODS

In this study, the gravure printing press is used to print the IT8.7/3 color target chart with Cyan, Magenta, Yellow, and Black foil inks on a blister foil substrate. Solvent-based Cyan, Magenta, Yellow, and Black inks are used to print the target chart. The electro-mechanical engraving has been used to engrave the IT8.7/3 color target chart on the gravure cylinders as a reference image. The reference image artwork IT8.7/3 is shown in Figure 1. Then, the prints are collected using the first engraved artwork from different runs using a gravure print press (P1). Similarly, two more gravure printing presses (P2, and P3) have been used to get print samples. The artwork has been engraved on the cylinder at 150 LPI screen ruling and 130° stylus angle.

To simulate the counterfeiting process, the original print samples (from printers P1, P2, P3) are scanned and new cylinders have been engraved for reprint. Figure 2 shows the step-by-step process for simulated counterfeiting process. All the process parameters, ink and blister foil samples remain unchanged. Then the reprinting has been done in the three printers and now the scanned reprint samples are named as R1, R2, R3.

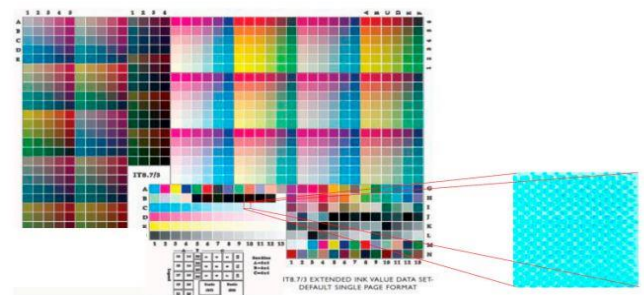
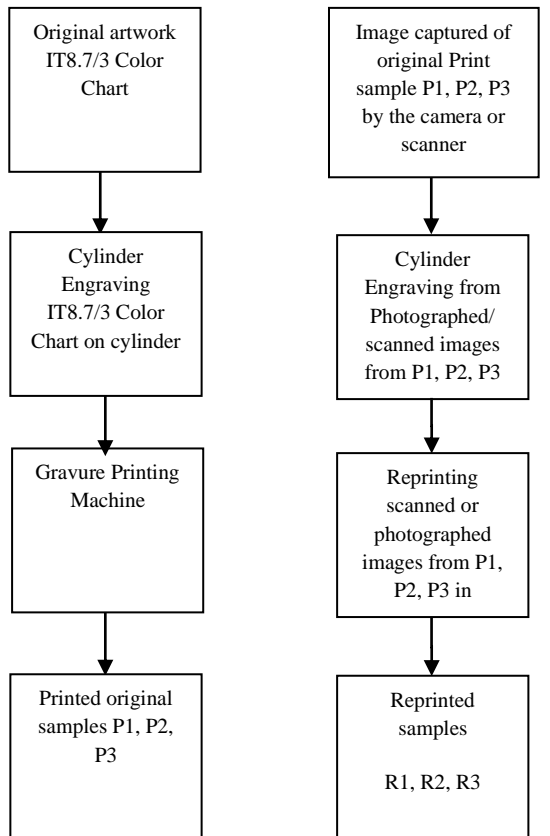


Figure 1: Artwork IT8.7/3 Color Chart reference image



Flowchart of Printing Process Flowchart of Simulated Counterfeiting Process

Figure 2: Original Print Process and Simulated Counterfeiting Process

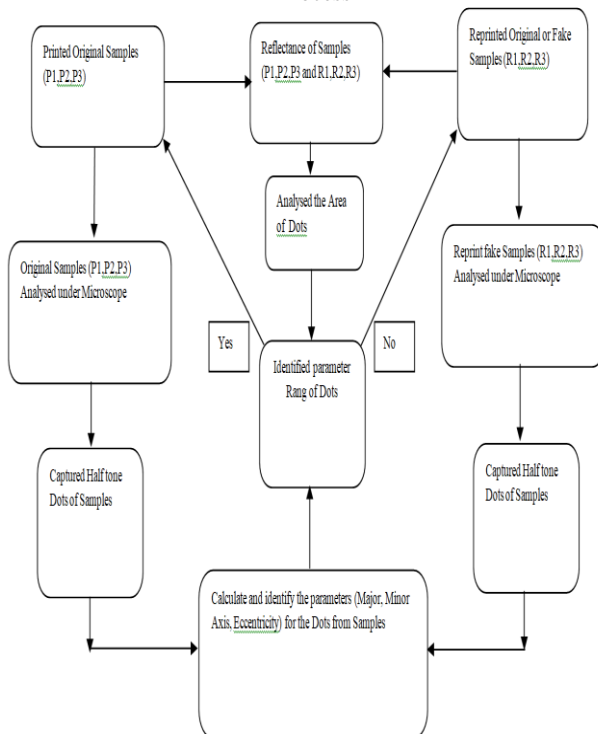


Figure 3: Flowchart of Experimental process

Figure 3 illustrate the steps of experimental process of this study.

A. MEASUREMENTS

The microscopic detail of printed dots and reprinted dots samples have been analyzed using the Lawrence & Mayo microscope with 4x zoom. The samples have been examined using the ScopeImage 9.0 microscopy software provided with the microscope. In this study, different dot areas (e.g., 20%, 40%,50%) of the colors cyan, magenta and yellow has been observed. To distinguish between printed and reprinted dots, parameters such as dot area, major axis, minor axis, and eccentricity have been used. To test the repeatability, the experiment has been run on several prints and reprint samples.

B. METHODOLOGY

In this study, edge detection has been applied to count the number of dots in print samples for a specific patch or tint percentage. The microscopic camera (model HDCE-X3) used to capture images of the dot samples for analysis purpose. The images are then transformed to grayscale or binary, and then canny edge detection has been applied on the images. The edges of the dot sample images have identified where there is a significant variation in the intensity of the pixels from foreground to background. The contours of the detected edge of the dots in the samples have taken for the next stage of the analysis. All of the outlines of the dots are created in white on a black background. The more or less circular-shaped object or dot contours have been detected using the circular Hough transform, which is a modification of the Hough transform. The contour detection method has been applied in this study to count dot objects independently of their shape. Then the major axis, minor axis, and eccentricity parameters of the observed dots are calculated using MATLAB functions. To begin, the 'Centroid' has been identified, and the 'MajorAxisLength' and 'MinorAxisLength' have been computed. The Eccentricity function is calculated for each dot object which is defined as the ratio of the length of an object's short (minor) axis to the length of its long (major) axis:

$$\text{Eccentricity} = c/a$$

Eq. 1

where 'a' is the length of semi-major axis and 'c' is the distance from center to the foci or focal.

– The outcome is a scale of object eccentricity that ranges from 0 to 1. Generally, the eccentricity value comes closer to 0 which means the shape is more like a circle, if the eccentricity value comes closer to 1 then the shape is more like an ellipse.

IV. THEORIES

In this present work, Murray-Davies Equation is used to calculate the dot area,

$$A = \frac{1-R_{ht}}{1-R_s}$$

Eq.2

Where A denotes the Dot Area of the particular tint, R_{ht} is the halftone color patch, and R_s is the reflectance of the solid color patch, This equation 2 may be expressed in terms of density as follows:

$$A = (1 - 10^{-D_{ht}}) / (1 - 10^{-D_s}) \quad \text{Eq.3}$$

Where, 'A' denotes Area of the particular tint percentage, D_{ht} is half tone color density and D_s is the density of solid color patch.

$$\text{Area of a single dot}(D_{AS}) = \frac{(A)}{(N_D)} \quad \text{Eq. 4}$$

Area of single dots have been calculated the area of a dot by equation 4, where D_{AS} is the area of a particular single dot of tint percentage, 'A' is the area of all dots in the tint percentage, N_D is the number of dots in the particular tint percentage.

The mean and standard deviation for the parameters dot areas, Major Axis, Minor Axis, and Eccentricity were obtained to find statistical analysis.

V. RESULTS AND DISCUSSION

Analyzing the dot structure parameters (dot areas, major axis, and minor axis) might be useful to distinguish the print samples from scanned reprint samples (which may be treated as counterfeited samples). In this study, print and reprint dot percentage color tints have captured using microscope, then converted to binary images. After that, the converted binary images have been used to obtain dot parameters for the print and reprint samples using MATLAB software. Figures 4 and 5 showed the dot structure of print-reprint samples and it defined a clear observation of print quality for both original-print and reprint (simulated counterfeited) dot percentages for cyan and magenta color patches.

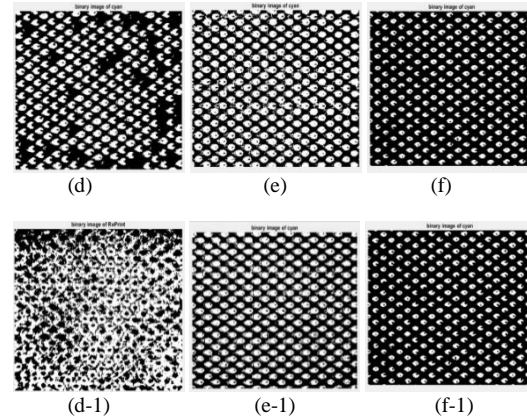
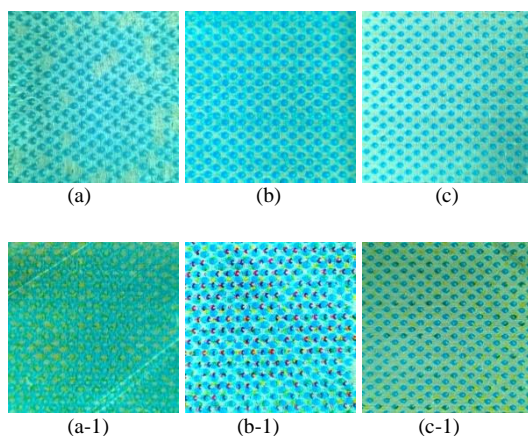


Figure 4: Analyzed image of Print ((a)Cyan 20% patch of Printer 1(P1), (b)Cyan 20% patch of Printer 2(P2), (c)Cyan 20% patch of Printer 3(P3)), (d)Binary image of Cyan20% patch of Printer 1(P1), (e)Binary image of Cyan20% patch of Printer 2(P2), (f)Binary image of Cyan20% patch of Printer 3(P3)) and Reprint ((a-1)Cyan 20% patch of Re-printer 1(R1), (b-1)Cyan 20% patch of Re-printer 2(R2), (c-1)Cyan 20% patch of Re-printer 3(R3)), (d-1)Binary image of Cyan20% patch of Re-printer 1(R1), (e-1)Binary image of Cyan20% patch of Re-printer 2(R2), (f-1)Binary image of Cyan20% patch of Re-printer 3(R3))

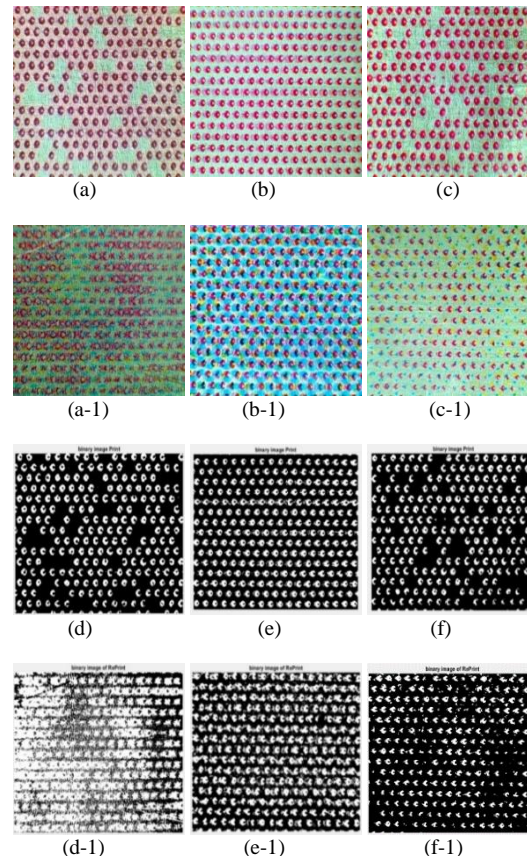


Figure 5: Analyzed image of Print ((a)Magenta 20% patch of Printer 1(P1), (b)Magenta 20% patch of Printer 2(P2), (c)Magenta 20% patch of Printer 3(P3)), (d)Binary image of Magenta 20% patch of Printer 1(P1), (e)Binary image of Magenta 20% patch of Printer 2(P2), (f)Binary image of Magenta 20% patch of Printer 3(P3)) and Re-print ((a-1) Magenta 20% patch of Re-printer 1(R1), (b-1) Magenta 20% patch of Re-printer 2(R2), (c-1) Magenta 20% patch of Re-printer 3(R3)), (d-1)Binary image of Magenta 20% patch of Re-printer 1(R1), (e-1)Binary image of Magenta 20% patch of Re-printer 2(R2), (f-1)Binary image of Magenta 20% patch of Re-printer 3(R3))

The experimental dot areas parameters for all print-reprint samples are depicted in Figures 6, 7 and 8. In the Figure 6, the average dots area for printers P1, P2, P3, and for reprints R1, R2, and R3 has been plotted for 20% cyan dots. It has been observed that the average dot areas of reprints are much higher than original prints. Similar results are observed in Figure 7 and 8 for 40% and 50% dot areas respectively.

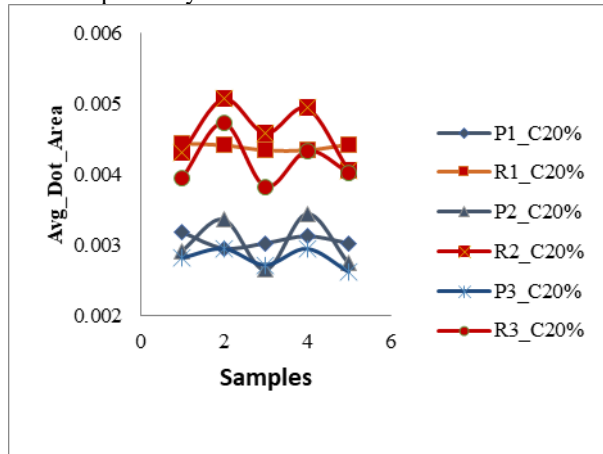


Figure 6: Cyan 20% patch Average Dot Area

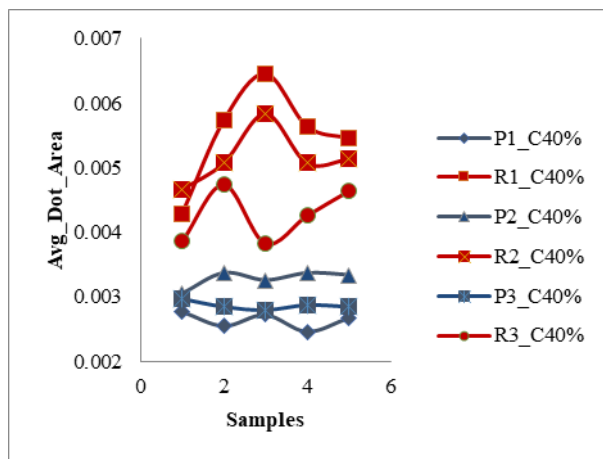


Figure 7: Cyan 40% patch Average Dot Area

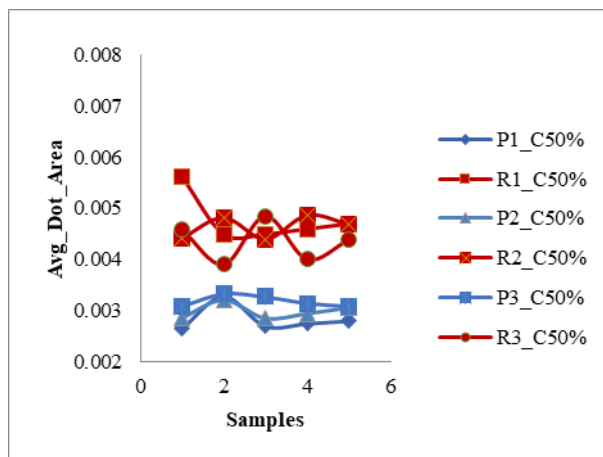


Figure 8: Cyan 50% patch Average Dot Area.

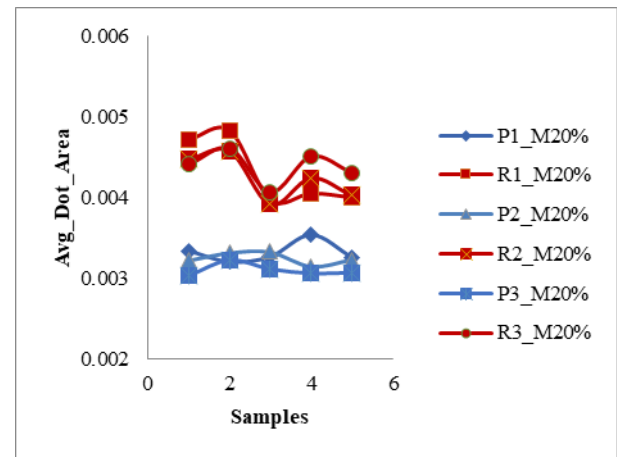


Figure 9: Magenta 20% patch Average Dot Area

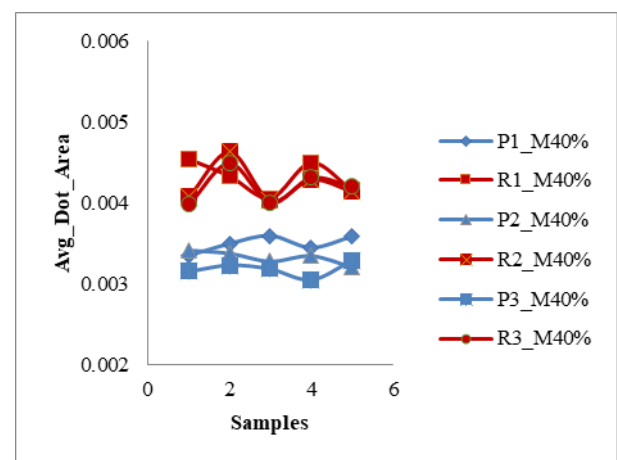


Figure 10: Magenta 40% patch Average Dot Area

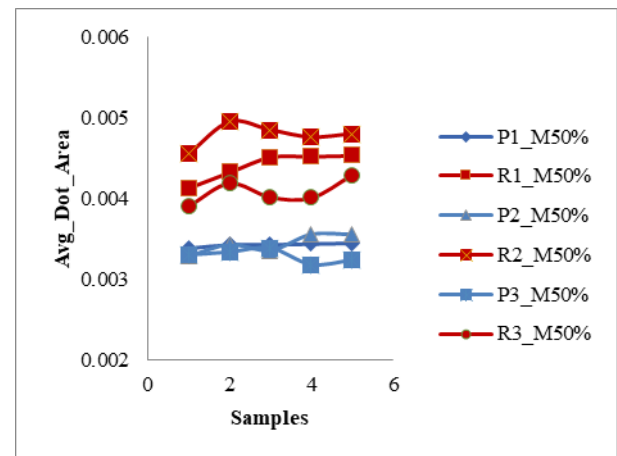


Figure 11: Magenta 50% patch Average Dot Area

Similarly, Figure 9, 10 and 11 showed that the dot areas for reprints are much higher than original prints for 20%, 40% and 50% dot areas of magenta respectively. Similarly, Figure 12, 13 and 14 showed that the dot areas for reprints are much higher than original prints for 20%, 40% and 50% dot areas of yellow respectively.

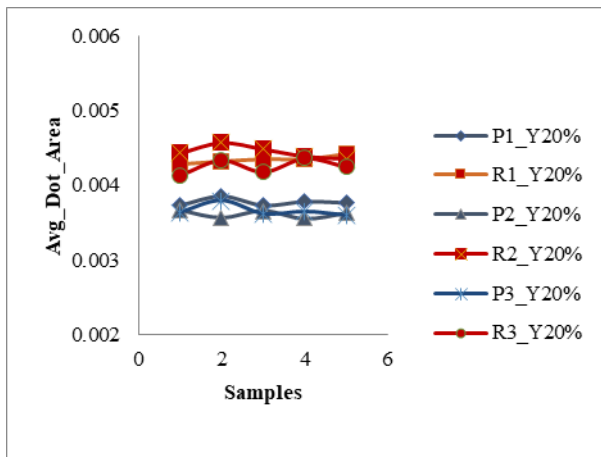


Figure 12: Yellow 20% patch Average Dot Area

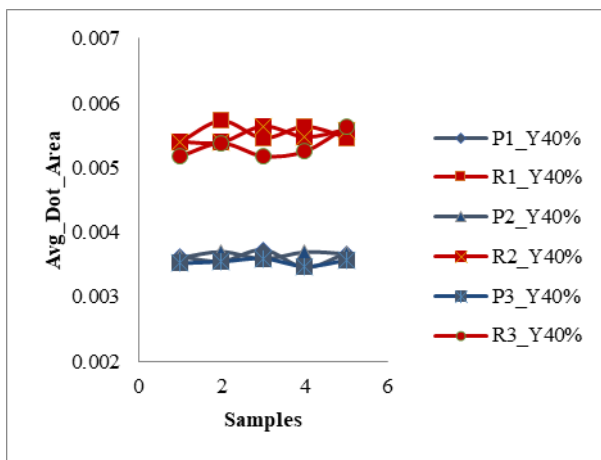


Figure 13: Yellow 40% patch Average Dot Area

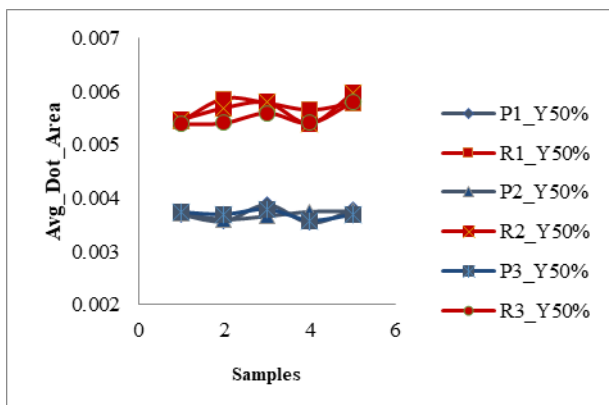
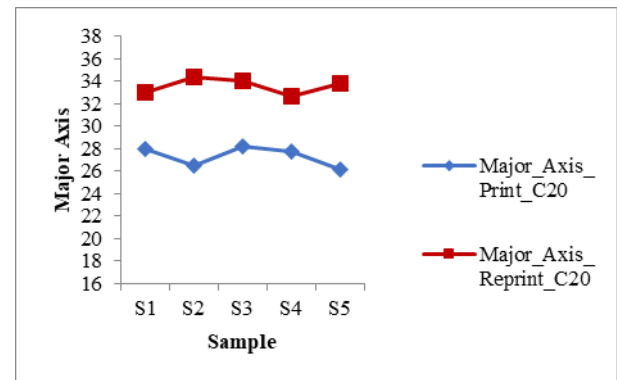


Figure 14: Yellow 50% patch Average Dot Area

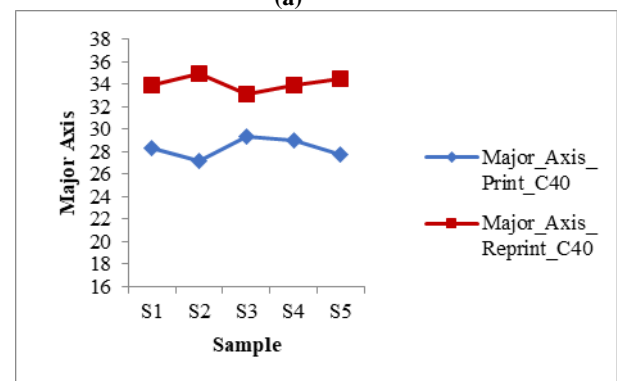
Two factors like major, minor axis, and eccentricity, have been evaluated for different dot areas of color patches for print and Reprint samples. Figure 15(a, b, c) showed that the major axis of reprints is much greater than the original prints for 20%, 40% and 50% dot areas of cyan respectively. Similar results have been shown for minor axis in Figure 16(a, b, c) for 20%, 40% and 50% dot areas of cyan respectively. In the Figure 17(a, b, c) showed that the eccentricity of cyan reprint dots has increased than print

dots. Similar kinds of results have been obtained for magenta prints.

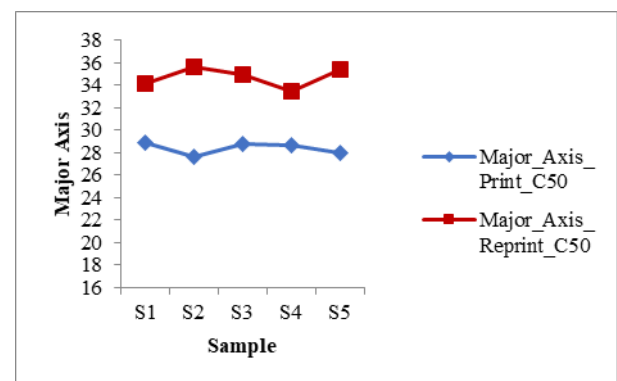
The stander deviation values of the major axis and minor axis for Reprint dots are more than that of original Prints.



(a)

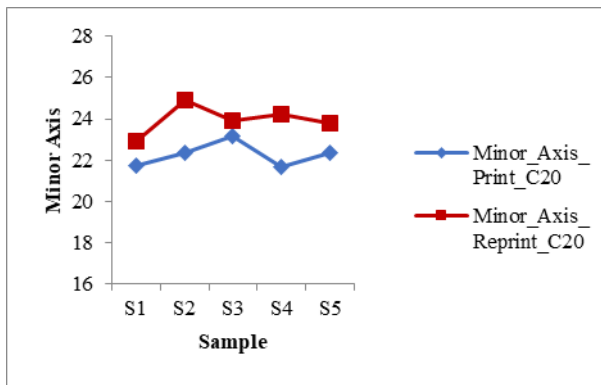


(b)

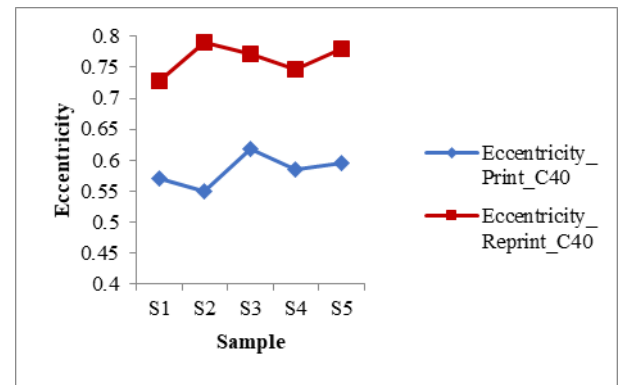


(c)

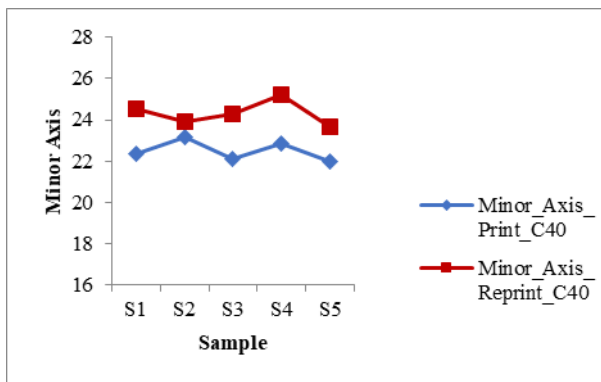
Figure 15(a, b, c): Major axis of cyan print and Reprint



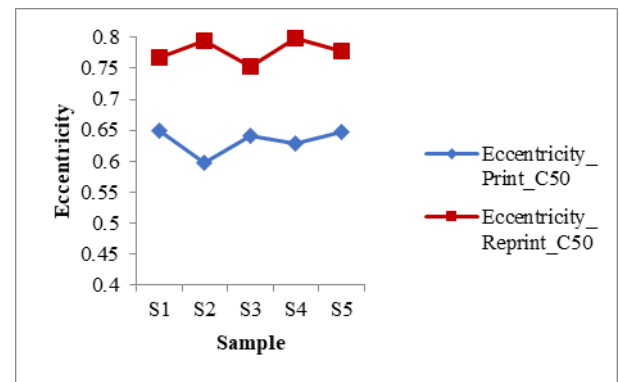
(a)



(b)



(b)



(c)

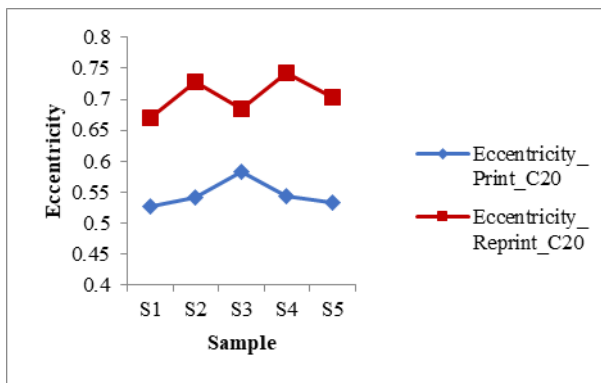
Figure 17(a, b, c): Eccentricity of cyan print and Reprint

Same as cyan dots the three parameters have been calculated for magenta print and reprint dots which have been shown in Figure 18, 19 below.

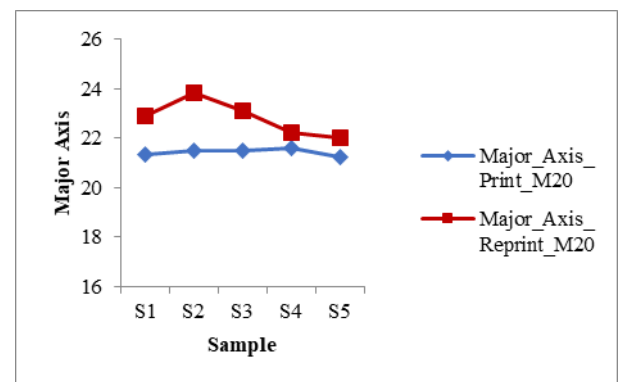
Here in the Figure 18(a, b, c) it has been observed that the average and standard deviation of major axis values of reprint samples have increased and in the Figure 19(a, b, c) it has showed that the average and standard deviation of minor axis values have also increased for Reprint samples than print samples.

In general, eccentricity aids in determining the shape's curvature. The eccentricity rises as the curvature decreases.

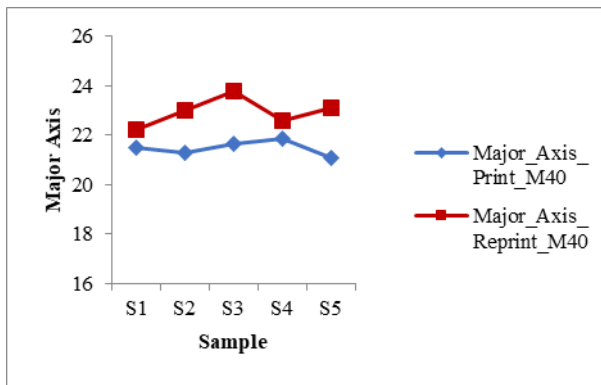
Figure 16(a, b, c): Minor axis of cyan print and Reprint



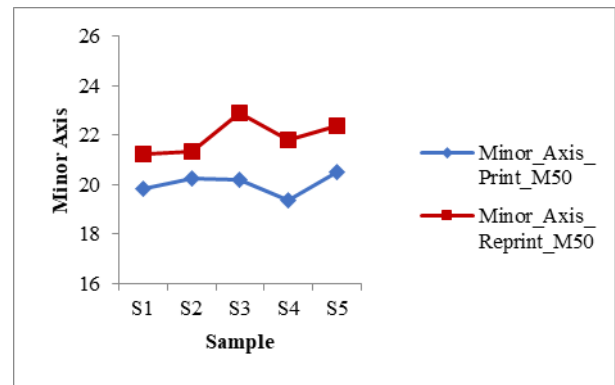
(a)



(a)

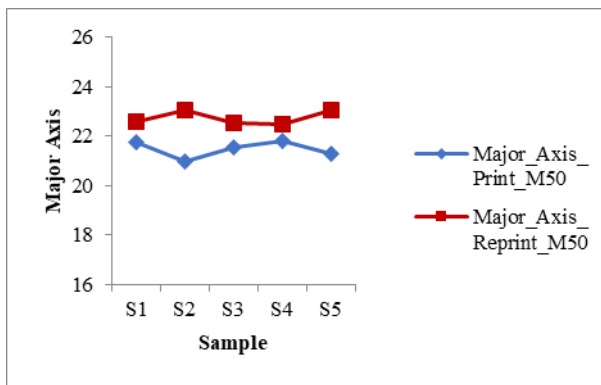


(b)



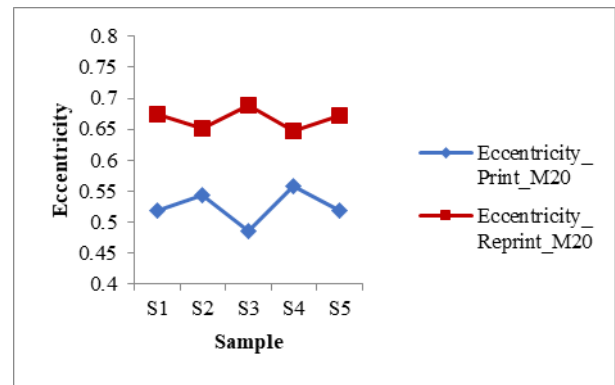
(c)

Figure 19(a, b, c): Minor axis of magenta print and Reprint

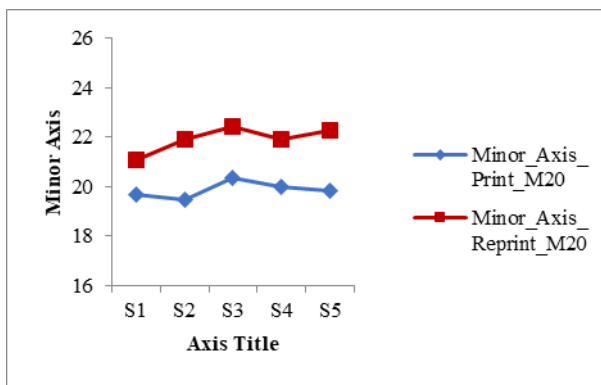


(c)

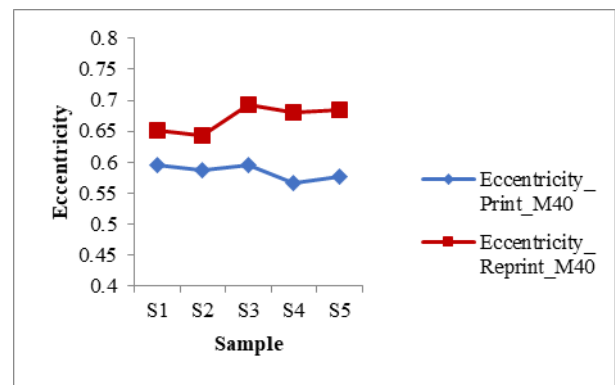
Figure 18(a, b, c): Major axis of magenta print and Reprint



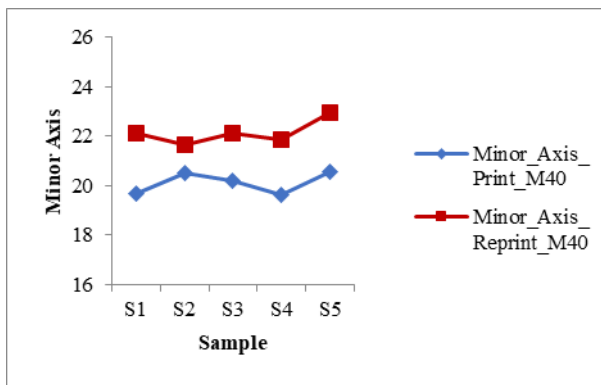
(a)



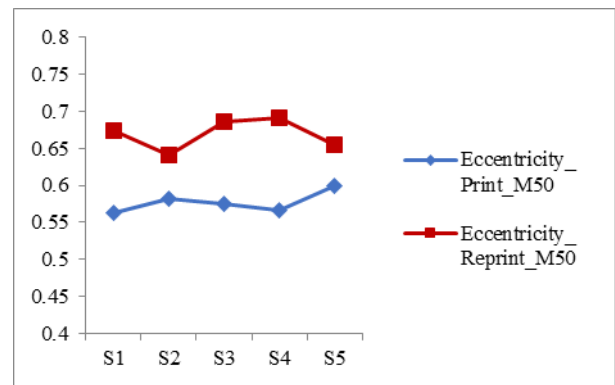
(a)



(b)



(b)



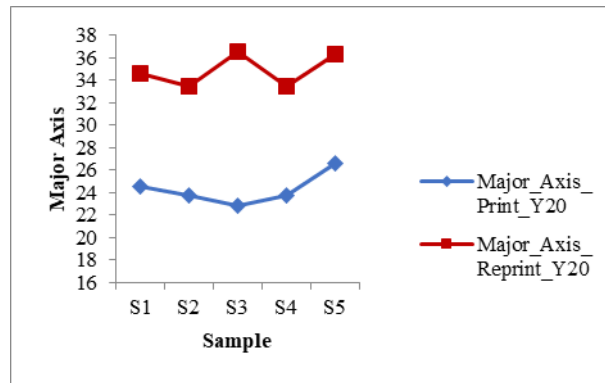
(c)

Figure 20(a, b, c): Eccentricity of magenta print and reprint

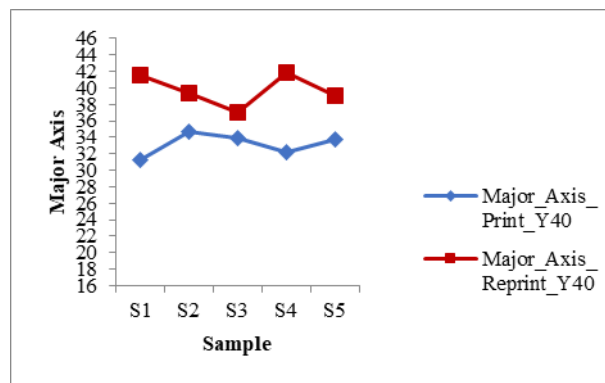
In Figure 20(a, b, c), the eccentricity of print and reprint dot samples have been plotted. The average dot eccentricity

has been increased for the reprint dot samples. It implies that the shape of the dots has been changed irregularly, for reprints in comparison to the print samples.

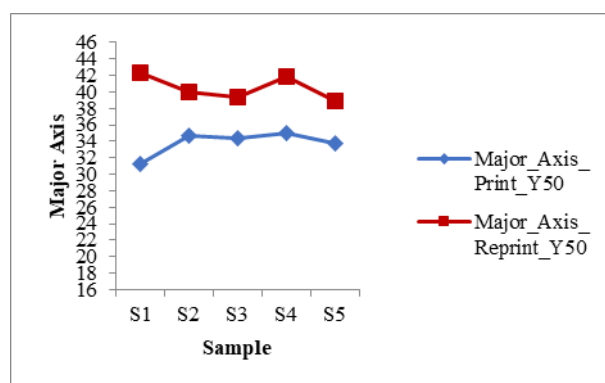
Similar results have been observed for yellow samples shown in the Figure 21(a, b, c), the average and standard deviation of major axis values of reprint samples have increased and in the Figure 22(a, b, c) the average and standard deviation of minor axis values have also increased for reprint samples than print samples.



(a)

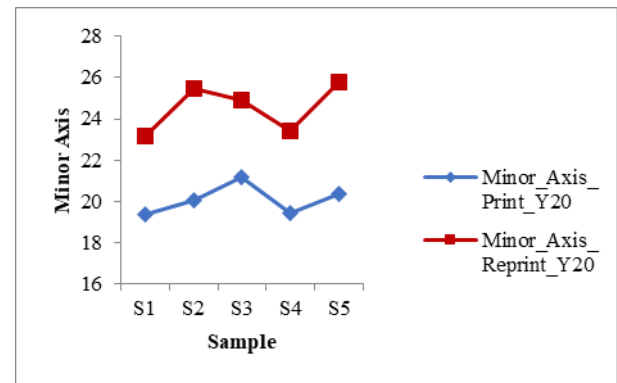


(b)

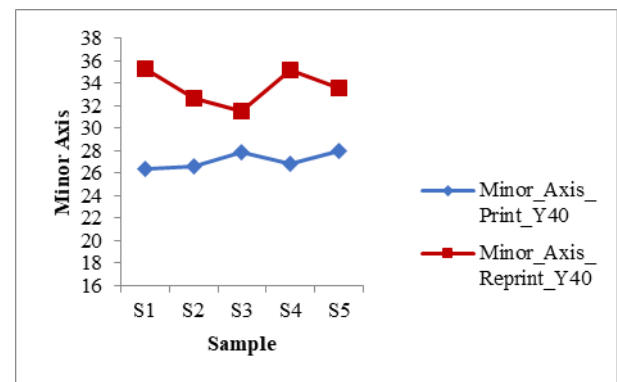


(c)

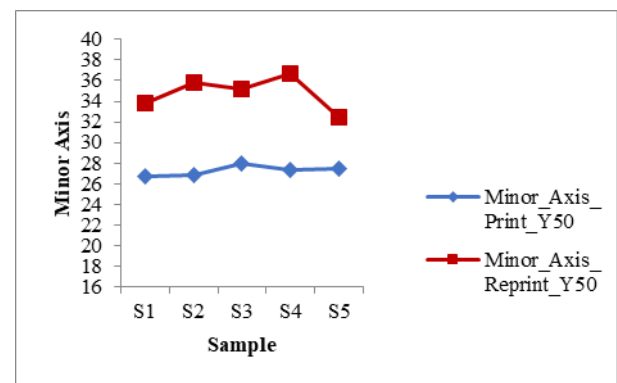
Figure 21(a, b, c): Major axis of yellow print and reprint



(a)



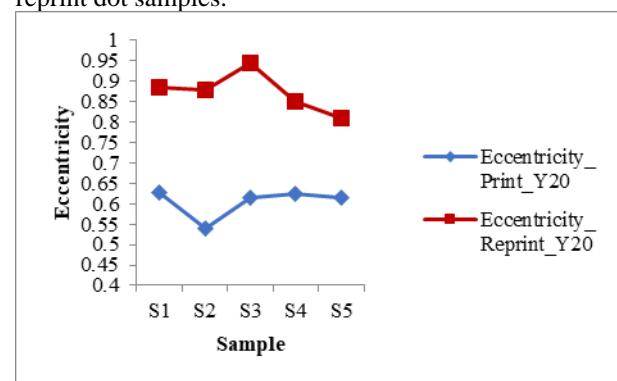
(b)



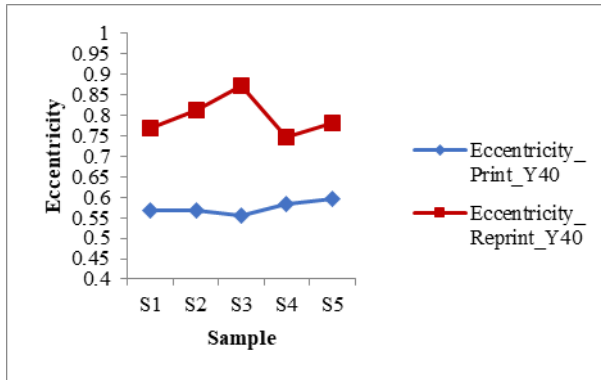
(c)

Figure 22(a, b, c): Minor axis of yellow print and reprint

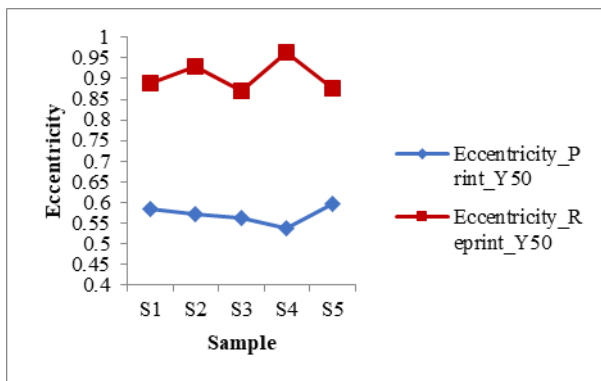
The eccentricity of print and reprint dot samples have been plotted in the Figure 23(a, b, c) for yellow print samples. The average dot eccentricity has been increased for the reprint dot samples.



(a)



(b)



(c)

Figure 23(a, b, c): Eccentricity of yellow print and reprint

In all cases, standard deviations are much higher for reprints than the original print samples.

From all observed variations it has been showed that the optical dot gain is unavoidable in case of reprints during imaging the original prints. It is not possible to eliminate the dot gain with adjustments because of the scattering of the substrate. Foil is smoother than other substrates. So, if it is significant in foil, then of course the difference will be more in other substrates like paper or plastic materials used for packaging.

VI. CONCLUSION

In this study, it has been observed that the dot area as well as the major axis, minor axis and eccentricity are increased for the Reprint sample in comparison to the print samples as indicated from microscopic studies of dot parameters. It may be possible to identify whether a medicine package is printed by the original manufacturer or their authorized printer, or the package is printed by the counterfeiters by these parameters. As soon as the prints will be copied and reprinted, dot gain will be included in the reprints which are irregular and cannot be completely eliminated. The increased standard deviation values of dot areas, major or minor axis and eccentricity for reprints in comparison to original prints shows that the homogeneity of the dots produced by original artwork will not be maintained after copying. As soon as the copying is done by any camera or scanner, optical dot gain will be incorporated which increases heterogeneity of the copied reprint samples.

This study is useful for determining the authenticity of printed package items that are on the market and is cost-effective.

In future, more color combinations will be studied. Special dot design may also be another area to explore. Apart from dot areas, dot angles may be other parameters of the study to ensure more authenticity of the prints.

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