ADULTERATION DETECTION IN PHARMACEUTICAL MATERIALS USING HYPERSPECTRAL DEVICE AND MACHINE LEARNING TECHNIQUES

Abstract

The pharmaceutical industry is expanding rapidly all over the world. The Indian pharmaceutical industry is one of the largest and most developed industry. Falsified or counterfeit drugs are one of the major problems in the world today. The World Health Organization (WHO) estimates that the global market for counterfeit medications generates about $200 billion annually (USD). Such a fake medications have the potential to not only cause significant disease but also death. Ensuring quality of medicine is becoming more important and challenging, this generates the need for more fast and smart technique to identify the fake medicines. Now a days the Remote Sensing techniques like Near Infrared Spectroscopic technique are widely used in pharmaceutical industry because of its numerous advantages. In this research work we analyze the different types of manufacturers Paracetamol tablets, excipients used for making tablets in pharmaceutical area by using hyperspectral non imaging data developed by using ASDFieldSpec4 Spectroradiometer, Chemometric and Statistical techniques, Preprocessing techniques like Savitzky golay filter combine with Second derivative, Standard normal variate techniques for noise removal and smoothing of spectral data. Hyperspectral dataset developed by ASDFieldSpec4 Spectroradiometer and Machine Learning and Deep Learning techniques was used to developed model that can predict the Paracetamol contents from tablets. Partial least square regression, Support Vector Machine, Random Forest, Decision tree, K-Nearest Neighbor machine

Authors

Rohit S. Gupta
Research Scholar
Department of Computer Science and IT
Dr. Babasaheb Ambedkar Marathwada University
Aurangabad (MS), India.
rohitgupta8844@gmail.com

Ratnadeep R. Deshmukh
Professor
Department of Computer Science and IT
Dr. Babasaheb Ambedkar Marathwada University
Aurangabad (MS), India.
rrdeshmukh.csit@bamu.ac.in

learning algorithms was used for development of model. The model is giving good prediction accuracy by using all the algorithm used in this model, out of this the PLSR algorithm and Random Forest given higher accuracy on original dataset and with PCA feature extraction algorithm compare to all other algorithms. The accuracy given by PLSR is 98% and by Random Forest is 99%.

Keywords: Counterfeit, ASDFieldSpec4, Machine Learning, Paracetamol Tablet, Excepients.

I. INTRODUCTION

Counterfeit medicines or Falsified medicines is one of the critical problem all over the world. According to the World Health Organization (WHO) the worldwide revenue of falsified medicines is around 200 billion dollars (USD). In pharmaceutical the counterfeiting of medicines can be type of underdoes, overdose or having wrong Active Pharmaceutical Ingredients (API) or the API is not present. Due to counterfeiting of medicines sometimes it causes to people to lose their health as well as money. Such a falsified medicines can not only cause serious illness but death also [1, 2, 3]. This generates the need for more fast and smart technique to fulfill the requirement. Ensuring quality of medicine is becoming more important and challenging. Pharmaceutical analysis deals with analysis of drugs, pharmaceutical substances and raw materials. It is devoted to stability testing, comparing related substances, determination of impurities. Assessment the quality of pharmaceutical dosage form, first to analyze the content qualitatively and quantitatively, then according to the results ensure that the given material is counterfeit drug or not. There where various analytical methods are used for analysis of pharmaceutical solid dosage forms. The methods are, UV/VIS spectrophotometric method, Near Infrared chemical Imaging (NIR-CI) method, Fluorimetric method, Titrimetric method, Chromatographic methods(Thin layer chromatography, Gas chromatography, High and ultra-performance, liquid chromatography), Capillary electrophoresis, Vibrational spectroscopes, Dynamic Nuclear Polarization Enhanced NMR, F Magic Angle Spinning NMR, NMR Micro imaging, Spatially Offset Raman Spectroscopy, Surface Enhanced Raman Spectroscopy with Microscopy, Terahertz Pulsed Spectroscopy Combined with Chemometric [4]. Hyperspectral Imaging and Traditional methods like GCMS and HPLC are popular and widely used in pharmaceutical industry. Hyperspectral imaging technique have widely demonstrated their usefulness in different area of interest in pharmaceutical research during the last decade. Hyperspectral imaging is imaging of a target at a large number of discrete wavelength. The hyperspectral image forms a "data cube" in which two dimensions represents spectral wavelength [5]. The laboratory famous chemical methods are Chromatography, Colorimetry, Gas Chromatography Mass Spectroscopy (GCMS), High Performance Liquid Chromatography (HPLC), and so on. In pharmaceutical industry chemical methods are mostly preferable like HPLC and GCMS. This method has some disadvantages like it consumes a lot of time for sample preparation and also it is nondestructive technique due to this we cannot reuse the sample [6]. Now a days Spectroscopic technique is most famous, effective and widely used in pharmaceutical industry due to its numerous advantages. It is fast and nondestructive and accurate technique preferably use for analyzing, finding counterfeit/fake, substandard medicines qualitatively and quantitatively analyzing the pharmaceutical materials [7]. There are many techniques available in pharmaceutical domain but Spectroscopic, Hyperspectral Imaging and Chemometric techniques are widely used.

1. **Spectroscopic Technique:** The term "spectroscopy" refers to a huge number of various types of procedures that use radiation to gather information on the composition and characteristics of matter, which is then used to address a wide range of analytical issues.8. Information on pharmaceutical solid dosage forms, such as tablets and powder, can be obtained using spectroscopy techniques. It can be used to analyses a substance's composition, identify contaminants, compare it to similar compounds, ascertain the molecular structure, etc. The field of agriculture can utilize spectroscopy. To determine the different components of soil, such as salt, moisture, carbon, etc., spectroscopy can be

utilized [8]. There are other infrared spectroscopy techniques that can be used with this methodology, including FTIR, ATR, DRIFT, NIR, Raman Spectroscopy, etc.

2. **Hyper Spectral Imaging Technique:** Over the past ten years, hyperspectral imaging has successfully demonstrated its value in numerous areas of pharmacological research. Imaging a target with a large number of distinct wavelengths is known as hyperspectral imaging. A hyperspectral image is essentially a "data cube" with two dimensions that represent different spectral wavelengths. Similar to spectral imaging, hyperspectral imaging gathers and analyses data from the entire electromagnetic spectrum. When used for both imaging and non-imaging data, hyperspectral imaging is often referred to as a remote sensing technique [9]. The goal of hyperspectral imaging is to find things, identify materials, and detect processes by obtaining the spectrum for each pixel in a scene's image. The pharmaceutical industry can employ hyperspectral imaging to spot fake medicines.

3. **Chromatographic Technique:** Chromatography is a method used in laboratories to separate mixtures. A fluid known as the mobile phase dissolves the mixture and transports it through a structure containing a different substance known as the stationary phase. Chromatography has both analytical and preparatory uses. Preparative chromatography is a type of purification since it is used to separate the components of a mixture for later use. Pharmaceutical analysis and formulation can be done using analytical chromatography, which is often utilized for smaller amounts of material. Chromatography can be used for both quantitative and qualitative analysis to purify, identify, and separate the components of a mixture. Column chromatography, ion-exchange chromatography, gel-permeation (molecular sieve) chromatography, affinity chromatography, paper chromatography, thin-layer chromatography, and dye-ligand chromatography are some examples of chromatography types [10].

   In this research work we used Hyperspectral non imaging technique. In non-imaging technique after acquisition of sample using instrument it will give the spectral signature of sample in the form of output. The graph of a function assigning the amount of reflected or emitted energy for each wavelength is called the spectral signature of a target. This signatures reveals detail information about the sample. ASD FieldSpec4 Standard-Res Spectroradiometer as spectroscopic non-imaging technique. The ASD FieldSpec4 Standard-Res Spectroradiometer is a state of art field spectrometer that allows spectral measuring and viewing in real time, enabling the user to easily assess the spectral signatures.

II. RELATED WORK

Sujit R Shinde, Karan Bhavsar, et.al. Developed a method for detection of counterfeit medicines using hyperspectral sensed data collected by VNIR hyperspectral device (350-1050nm). For analysis and development of model the Multilayer Perceptron Classifier classification method was used. Accuracy was given by model is Overall 90% accuracy got [11].

Alexander Becht, Curd Schollmayer, Yulia Monakhova, et.al. Developed a method for Tracing the origin of paracetamol tablets by using near-infrared, mid-infrared, and nuclear

magnetic resonance spectroscopy combine with machine learning principal component analysis and linear discriminant analysis techniques. The Principal Component Analysis (PCA), Nuclear Magnetic Resonance (NMR), Linear Discriminant Analysis (LDA) techniques given good results. NMR and LDA give 94.6% and 98.7% accuracy respectively [12].

Dana Maria Muntean, Cristian Alecu, et.al. used traditional method HPLC, HPLC, Partial Least Square(PLS), Chemometric methods a for Simultanious Quantification of Paracetamol and Caffeine in Powder Blends for Tableting by NIR-Chemometry, Analysis of results with, Overall 97% Accuracy got [13].

M. Alcala, Marcelo Blanco, Daniel Moyano, Neville W. Broad, Nada Brien, et.al. Developed a method for Discrimination between illegal generic and authentic pharmaceutical product. Author used novel hand-held miniature near infrared spectrometer for qualitative and quantitative pharmaceutical analysis. Author also developed Spectral library for raw material identification. Machine learning technique PCA and Savitzky golay fiter with IInd derivative was used for preprocess and analysis of data. Overall accuracy was given proposed model is 97% [14].

Klara Degardin, Aurelie Guillemain, Nicole Viegas Guerreiro, et.al. Developed a model for identification of counterfeit medicines and developed hyperspectral data using near infrared spectroscopy for counterfeiting detection in pharmaceutical tablets. The Chemometric methods SNV, Savitzky galay filter with IInd derivative was used for preprocessing of spectral data and PCA, SVM, KNN, DA machine learning algorithms was used for developing models and classification of data. Overall accuracy given by SVM and KNN is 100% and 78.4% respectively [15].

Graham Lawson, John Ogwu, Sangeeta Tanna used ATR-FTIR and reflectance infrared spectroscopy combine with UV-Visible Spectrometer, Multivariate PLS model for Quantitative screening to distinguish between genuine and falsified or substandard paracetamol tablets and Pharmaceutical ingredient for the rapid identification of substandard and falsified medicines [16].

Xiao Meng Chong, Wen-Bo Zou, Shang-chen Yao, et.al. Used Diffuse Reflectance Near Infrared Spectroscopy Rapid analysis of the quality of Amoxicillin and Clavulanate Potassium Tablets Using, to evaluate the quality of Amoxicilin and Clavulanate potassium tablet quality. Cycle-closed dimer model, PLS method. Overall accuracy 94.6% [17].

Mokhtar A. Al-Awadhi and Ratnadeep R. Deshmukh, developed a method for Honey Classification and its botanical origins using Hyperspectral Imaging and Machine Learning techniques. SVM, KNN, LDA machine learning algorithms was used for hyperspectral imaging based classification. Accuracy was given by the model was 95.3% and 92.8% respectively [18].

Rohit Gupta, et.al. Developed a method to analyze the Ten different types of Paracetamol tablets purchased from local pharmacies. The Gas Chromatography and Mass Spectroscopy method was used by the author. According to the results, paracetamol's retention time of 8.045 seconds and molecular weight of 151.00, along with a sharp single

line in the spectrum, indicate the presence of paracetamol with a low concentration of other micro-constituents. Out of 10 samples, the spectra of samples 2, 4, 5, and 6 show paracetamol to be 95% pure with a low concentration of other excipients. The paracetamol peak was missing from the reported spectra in sample number 9, which means the tablet does not contain any paracetamol and does not contain any active ingredients [19].

Rohit S. Gupta et.al. Utilized Near Infrared Sensor in the form of ASD FieldSpec4 Spectroradiometer having 350-2500 nanometer broad spectral range. Spectral database in the form of spectral signature of pharmaceutical samples was collected by ASD FieldSpec4 Spectroradiometer. The chemometrics and Savitzky golay filter with First and Second derivative preprocessing techniques was used for sample preparation. PLSR Regression model developed and used for analysis of pharmaceutical data. For validation of results, the cross validation having 10 fold technique was used. The model showed the good results and high accuracy as 99% [20].

Abdulla A. Omeer, et.al. Developed classification models for hyperspectral data using deep neural networks. Ten leaves from invasive plants were measured for their spectrum reflectance using an ASD FieldSpec4 standard Hi-Res equipment. One-dimensional convolutional neural network (1D CNN) and convolutional long short term memory (CNN-LSTM) are two different forms of deep neural networks (DNN) that were used. Multilayer perceptron (MLP), random forest (RF), and support vector machine (SVM) are three existing models that we proposed and compared the performance of with the two new models. The CNN-LSTM model outperforms all other models in terms of discrimination accuracy, scoring a 99.3% total test accuracy and an F1_score of 0.98 [21].

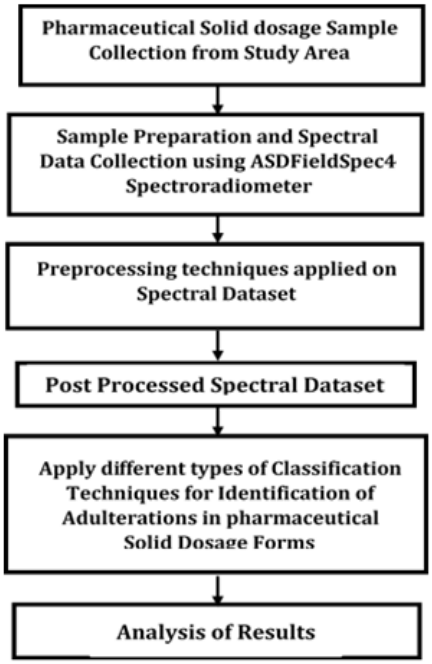
Priyanka Uttamrao Randive et.al. Analyses how illness effects on cotton plants. Data on the hyperspectral properties of cotton plants were gathered using the ASD Field- Spec4 Spectroradiometer equipment. Cotton plant leaves are taken from the Harsul Sawangi regions of Aurangabad City, Maharashtra, India, both healthy and diseased. Statistics are used to compare spectral data. Different zones of electromagnetic radiation are differentiated between healthy and sick leaves. Blue (400 nm to 525 nm), Green (525 nm to 605 nm), Yellow (605 nm to 655 nm), Red (655 nm to 750 nm), and NIR (750 nm to 1800 nm) are the ranges of region. The healthy leaves of the cotton plant had a higher reflectance than the damaged leaves [22].

The ASDFieldSpec4 Spectroradiometer is a spectroscopic device that having various application in Agriculture, Drug and Pharmaceutical industry, Food Industry, Dairy product and so on. In the Food and Drug industry, the spectroscopic techniques combine with machine learning and statistical techniques showed their importance. It gives good accuracy because of its numerous advantages. It is nondestructive techniques so that we can reuse the sample used for data collection. The various author worked on adulteration detection in Medicines, Coconut Milk, Honey and so on.

III. PROPOSED METHODOLOGY AND DATA COLLECTION

In this research work first we collect the samples from study area and then prepare those samples with some standard procedure. Hyperspectral data was collect in the controlled

environment by using ASDFieldSpec4 Spectroradiometer that having 350-2500 nanometer spectral range. Figure1 shows the proposed methodology used in this research work.



1. **Study Area and Sample Collection:** The plain Paracetamol tablets of different types of manufacturers are purchased from various pharmacies from the locations of Waluj, Padegaon, Garkheda, Jubly Park, Begumpura located in Aurangabad City, Maharashtra, India as showed in figure2.

Figure 2: Study Area

Pure Paracetamol as Active Pharmaceutical Ingredients (API) and Common Excipients are obtained from Department of Chemical Technology, Dr. Babasaheb Ambedkar Marathwada University, Aurangabad (MS) and Srinath College of Pharmacy,

Hitech college campus, Bajajnagar, Aurangabad (MS) as a gift sample for research purpose.

2. **Sample Preparation and Data Collection**Total 20 types of Paracetamol tablets that having 500mg of paracetamol prescribed on medicines was purchased from study area from various pharmacies. From 20 tablets each sample given label as Sample 1 to Sample 20. Sample1 (having 20 tablets) were crushed using mortar and pestle and converted to the fine powder. Likewise, all 20 Samples are prepared as fine powder. Weighing machine was used for weighing weight of each sample and it was noted according to the sample number. Every sample was packed in airtight bag and labeled it according to sample number. We have collected spectral signature of various paracetamol tablets, standard paracetamol as API and 20 types of common excipients by using ASDFieldSpec4 Spectroradiometer and RS3 Software. We collected Spectral database of samples in controlled environment laboratory, it was dark room specially designed for spectral data collection of samples because outside noise and light will effect on spectral signature. In laboratory complete Spectroradiometer setup is shown in figure3.

Figure 3: ASDFieldSpec4 Laboratory Setup

Before Spectral data collection of sample, the ASDFieldSpec4 Spectroradiometer should warmup for 30 minutes, and we did this. Distance between light source and spectral gun is kept 60cm. Distance between spectral gun and sample is set to 10cm. For covering the complete area of sample the 8-degree field of view (FOV) was used. Finally, for data collection RS3 software was used for capturing spectral signatures. To optimize and calibrate the device white reference panel reading have been taken.

3. **Dataset Preparation:** The objective of the experiment is to developed the machine learning model that can detect the adulteration level (0%, 25%, 50%,75%) of given sample. As shown in Table2, from Sample Preparation and Data Collection section samples was prepared and did the following steps from 1-4.

- Original Medicine Powder
- Original Medicine Powder is removed ~25% of weight and Mixed with ~25% of Calcium Carbonate

- Original Medicine Powder is removed ~50% of weight and Mixed with ~50% of Calcium Carbonate
- Original Medicine Powder is removed ~75% of weight and Mixed with ~75% of CalciumCarbonate

Finally, the dataset was prepared as shown in below table1.

Table1: Dataset Classes Label

Class Label	Values
1	Original Medicine Powder
2	25% Adulterated (Low)
3	50% Adulterated (Medium)
4	75% Adulterated (High)

4. **Instrument: ASDFieldSpec4 Spectroradiometer:** ASDFieldspec4 Spectroradiometer is used for capturing hyperspectral data of samples. The device have many applications in Remote Sensing domain and it can be used for different types of applications like. Geology and Mining, Defense, Environmental, Material Analysis, Agriculture, etc. From Agriculture and Material Analysis the ASDFieldSpec4 device is using for Soil, Plant, Biomass, Commercial Agriculture, Food analysis, Nutraceuticals and Dietary Supplements, Pharmaceuticals analysis[16, 17, 18]. In this research work, we used this device for Pharmaceuticals applications. The below Figure4 and Table2 shows the major specification of ASDFieldSpec4 Spectroradiometer device.

Table 2: Specificatio of ASDFieldSpec4 device

Spectroradiometer Name	ASD Field Spec 4 Std. Resolution Spectroradiometer
Spectral Range	350-2500 nanometer
Sampling Interval	1.5 nm @350-1000nm , 2nm @ 1001- 2500nm
Spectral Resolution	3 nm @ 700nm , 10nm @ 1400/2100nm
Detectors	VNIR (350-1000 nm), SWIR1 (1001- 1800nm), SWIR2 (1801-2500nm)
Input	Direct Mounted Fiber optic (25 degree FOV), optional narrowed FOV fiber optic lens available to change the FOV
Wavelength Accuracy	0.5nm

Figure4: ASDFieldSpec4 device

5. **Software Used:** In this research work, we used RS3 software was used for acquision of Spectral signature of samples. ViewSpec Pro software was used for converting Spectral signature graphs to ASCII/numeric format for analysis of spectral signature and also used to apply statistical process and chemometric process like Averageing, Mean, Max, Preprocessing techniques. For developing machine learning model for classification as front end Spider tool was used combine with Python language with essential libraries.

IV. RESULTS AND DISCUSSION

1. **Preprocessing:** Hyperspectral dataset prepared by ASDFieldSpec4 device need to be preprocessed for removing irrelevant spectral bands, noise and smoothing of spectral signature curves. According to the previous study and their efficient results the Savitzky golay filter combined with second derivatives and Standard normal variate (SNV) is widely used for NIR dataset. So in this research we applied Savitzky golay filter combine with second derivative and SNV as a preprocessing technique for dataset. Figure 5 shows the Mean of Paracetamol tablets and Pure Paracetamol Spectral signature and Figure6 shows the after preprocessed applied on spectral signature.

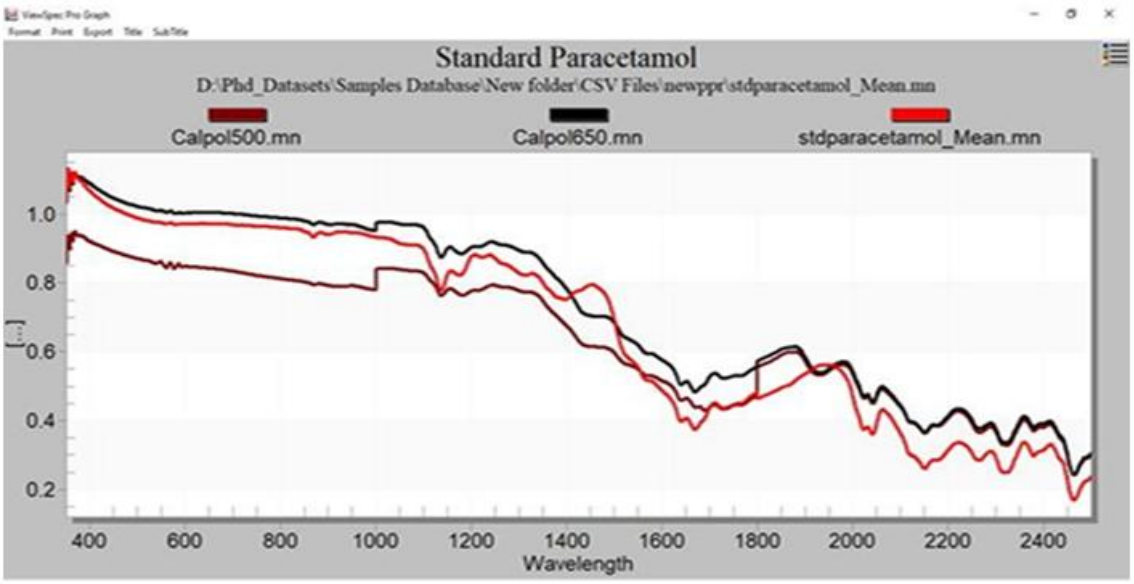


Figure5: Spectral Signature of Tablet and Pure Paracetamol

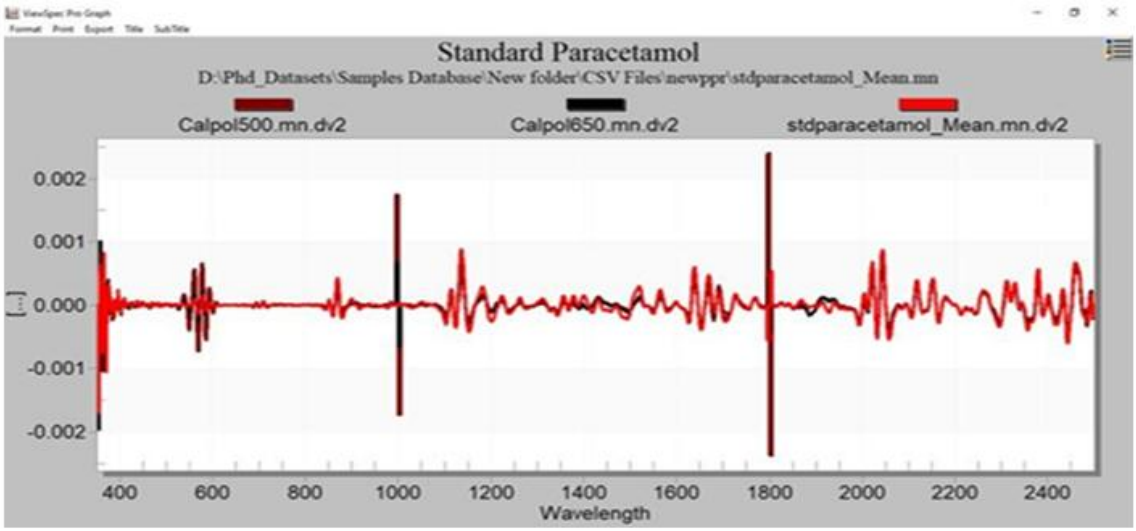


Figure 6: Preprocessed Spectral Signature of Tablets and Paracetamol

2. **Feature Extraction:** For classification task the feature extraction is essential step because it enhance the accuracy and performance of the classification model by extracting only significant bands from the data, this individual bands called features. There are many machine learning algorithms and statistical methods are available those can be used for feature extraction. From which the machine learning technique are widely used. According to the previous study basically there are two machine learning techniques are available, Supervised and Unsupervised technique. Principal Component Analysis (PCA) is one type of unsupervised algorithm. It do not require class labels at the time of feature extraction. Similarly the Linear Discriminant Analysis (LDA) is one type of supervised algorithm and it's required the class labels for feature extraction. Previous work showed that PCA and LDA are efficient methods for extracting the significant features form hyperspectral non imaging data of in pharmaceutical domain as well as in material analysis. So due to this in this research work we used both LDA and PCA techniques for feature extraction and accuracy assessment.

3. **Classification and Results**: After preparation of dataset, the model was developed having five classifiers with feature extraction techniques using Linear Discriminant Analysis (LDA) and Principal Component Analysis (PCA). Random Forest (RF), K Nearest Neighbor (KNN) and Decision Tree classification algorithms given higher accuracy on original dataset and using PCA feature extraction technique compare to other classifiers. As compare to LDA Feature extraction technique, PCA performed well for all classifiers. Support Vector Machine (SVM) is a linear model for classification and regression problems, here it gives 94% accuracy compare to SVM with Radial Basis Function (RBF) kernel, and it gives 83% accuracy. The SVM, KNN, RF and DT can be use for classification as well as regression problems but in this research work we use this algorithms for classification purpose and out of this the RF and DT given the higher accuracy compare to all other algorithms. The below table3 shows the performance of various classifiers on original dataset and using LDA and PCA Feature extractor techniques.

Table 3: Machine Learning Model Results

Sr.no	Machine Learning Algorithms	Machine Learning Model Accuracy		
		Original Data	LDA	PCA
1	KNN	0.9869	0.9256	0.9872
2	SVM Linear	0.9428	0.9250	0.8981
3	SVM RBF	0.8362	0.9263	0.9716
4	DT	0.9855	0.9181	0.9827
5	RF	0.9962	0.9241	0.9975

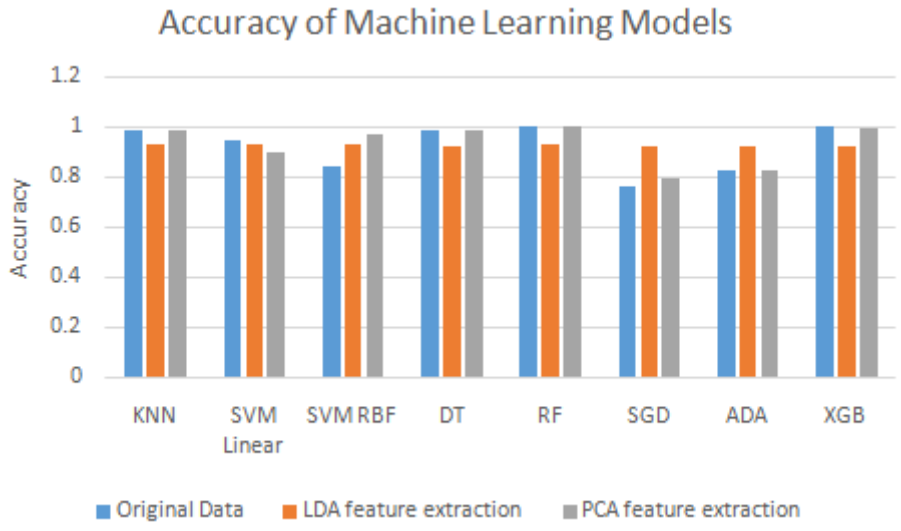


Figure 7: Accuracy Graph of Machine Learning Model

The table3 and figure7 shows results of various machine learning algorithm applied in this experiments on original dataset and after applying LDA and PCA feature extraction on original dataset in tabular and graphical format. In this experiment the Random forest machine learning algorithm given higher accuracy that is 99% on original dataset as well as with PCA feature extractor.

V. CONCLUSION

Adulteration detection from pharmaceutical materials was not easy by using traditional laboratric methods. In this research work we used hyperspectral device for generating hyperpsetral data from a pharmaceutical samples and with the help of chemometric and machine learning techniques. Different types of paracetamol tablets was used as sample and for adulteration purpose calcium carbonate as common excepients was used. The ASDFieldSpec4 Spectrocopic device was used for creation of hyperspectral database from samples. The hyperspectral dataset was analysed with the help of some chemometric and preprocessing techniques. After this dataset was used for training the machine learning models. Different types feature extraction techniques and Machine learning model was used to train the models and used for detection of adulteration in pharmaceutical

materials. The table3 showed the reults given by the models, out of this the Random forest showed the higher accuracy it is 99%.

VI. ACKNOWLEDGMENT

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