

# Counterfeit Drug Detection Using Deep Learning and Synthetic Data Generation: A Hybrid Approach

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## Abstract

Counterfeit pharmaceuticals pose a critical threat to global public health, particularly in low- and middle-income countries where regulatory oversight and access to advanced authentication tools are limited. This study presents a comprehensive deep learning framework for automated counterfeit drug detection that addresses the persistent challenge of limited authentic counterfeit training data through synthetic data generation. A hybrid dataset was constructed by combining real-world pharmaceutical images from public repositories with synthetically generated counterfeit images produced using Stable Diffusion XL. Five convolutional neural network architectures—ResNet50, InceptionV3, VGG16, EfficientNetB0, and MobileNetV2—were evaluated under real-only, synthetic-only, and hybrid training regimes. The hybrid approach achieved the best performance, with ResNet50 attaining 97.0% accuracy and an AUC-ROC of 0.993, significantly outperforming models trained on real data alone. Integration of optical character recognition for batch number and expiration date verification further improved system accuracy to 98.2%. A mobile application prototype was developed to demonstrate deployment feasibility, achieving sub-200 ms inference time after model optimization. The results confirm that carefully designed synthetic data generation, when combined with real-world data, substantially improves robustness, generalization, and practical usability of AI-based pharmaceutical authentication systems.

**Keywords:** Counterfeit drug detection; deep learning; synthetic data generation; diffusion models; computer vision; pharmaceutical authentication; transfer learning.

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## Introduction

The global proliferation of counterfeit pharmaceuticals represents a major public health and economic challenge [1]. The World Health Organization estimates that up to 10% of medicines in low- and middle-income countries are substandard or falsified, with considerably higher prevalence in certain regions [2]. Counterfeit drugs can contain incorrect dosages, harmful substances, or no active ingredients at all, leading to treatment failure, drug resistance, and preventable mortality [3]. Traditional authentication methods such as chemical assays, spectroscopy, and laboratory testing are accurate but often expensive, slow, and inaccessible outside specialized facilities [4-5].

Recent advances in artificial intelligence and computer vision have enabled automated, image-based drug authentication using convolutional neural networks [6]. However, the effectiveness of such systems is constrained by the scarcity of labelled counterfeit drug images [7]. Genuine counterfeit samples are difficult to obtain due to legal, ethical, and logistical barriers, and their visual diversity further complicates dataset construction [8]. This study addresses these limitations by introducing a hybrid training strategy that combines real-world pharmaceutical images with high-quality synthetic counterfeit images generated using a state-of-the-art diffusion model [9].

Prior research on counterfeit drug detection has explored spectroscopic methods combined with machine learning, computer vision systems integrated with blockchain, and mobile-based detection using lightweight CNNs [10]. While spectroscopic approaches report high accuracy, they require specialized equipment. Vision-based approaches are more accessible but typically suffer from limited training data and reduced generalization [11]. Multi-modal systems combining visual and textual verification have shown promise but remain underexplored at scale [12].

Synthetic data generation has emerged as an effective solution to data scarcity in medical imaging and other constrained domains [13]. Early work [14] relied on generative adversarial networks, while more recent studies demonstrate that diffusion models produce superior image quality and diversity [15-16]. However, the application of diffusion-based synthetic data generation to pharmaceutical authentication remains limited. This study bridges that gap by leveraging Stable Diffusion XL to generate realistic counterfeit drug images and systematically evaluating their impact on model performance.

## Methodology

An experimental research design was adopted, consisting of data collection, synthetic data generation, data augmentation, model training, and evaluation. Real-world images were obtained from publicly available Mendeley and Kaggle datasets [17-18] containing authentic and counterfeit pharmaceutical products. Synthetic counterfeit images were generated using Stable Diffusion XL with carefully engineered prompts that emphasized common counterfeiting defects such as poor print quality, misaligned text, color inconsistencies, and packaging irregularities.

All images were resized to  $224 \times 224$  pixels and split into training, validation, and test sets using stratified sampling. Data augmentation was applied during training using the Albumentations framework [19] to simulate real-world variations in lighting, perspective, blur, noise, and compression artifacts. Five CNN architectures pre-trained on ImageNet were fine-tuned using transfer learning. Models were trained under three conditions: real data only, synthetic data only, and a hybrid combination of both.

Performance was evaluated using accuracy, precision, recall, F1-score, specificity, AUC-ROC, and Cohen's kappa. Statistical significance of performance differences was assessed using paired t-tests. An OCR module [20] based on Tesseract was integrated to extract and verify batch numbers, expiration dates, and manufacturer information, enabling multi-modal verification.

## Results and Discussion

Table 1 presents the classification performance of all evaluated CNN architectures when trained exclusively on real-world pharmaceutical images. Table 2 reports results for models trained only on synthetically generated images, while Table 3 summarizes performance under the proposed hybrid training strategy. Additional tables present ablation, OCR integration, and computational performance results.

**Table 1.** Model Performance Using Real Data Only

| Model          | Accuracy (%) | Precision (%) | Recall (%) | F1-Score (%) | AUC-ROC |
|----------------|--------------|---------------|------------|--------------|---------|
| ResNet50       | 92.3         | 91.8          | 92.7       | 92.2         | 0.968   |
| InceptionV3    | 89.7         | 88.9          | 90.3       | 89.6         | 0.951   |
| VGG16          | 87.4         | 86.5          | 88.1       | 87.3         | 0.942   |
| EfficientNetB0 | 90.1         | 89.6          | 90.5       | 90.0         | 0.956   |
| MobileNetV2    | 85.8         | 84.7          | 86.8       | 85.7         | 0.928   |

**Table 2.** Model Performance Using Synthetic Data Only

| Model          | Accuracy (%) | Precision (%) | Recall (%) | F1-Score (%) | AUC-ROC |
|----------------|--------------|---------------|------------|--------------|---------|
| ResNet50       | 84.6         | 83.2          | 85.9       | 84.5         | 0.912   |
| InceptionV3    | 82.1         | 80.8          | 83.3       | 82.0         | 0.898   |
| VGG16          | 79.3         | 77.9          | 80.6       | 79.2         | 0.881   |
| EfficientNetB0 | 83.4         | 82.1          | 84.6       | 83.3         | 0.905   |
| MobileNetV2    | 77.8         | 76.4          | 79.1       | 77.7         | 0.869   |

**Table 3.** Model Performance Using Hybrid (Real + Synthetic) Data

| Model          | Accuracy (%) | Precision (%) | Recall (%) | F1-Score (%) | AUC-ROC |
|----------------|--------------|---------------|------------|--------------|---------|
| ResNet50       | 97.0         | 96.8          | 97.2       | 97.0         | 0.993   |
| InceptionV3    | 94.3         | 93.9          | 94.7       | 94.3         | 0.981   |
| VGG16          | 91.8         | 91.2          | 92.3       | 91.7         | 0.971   |
| EfficientNetB0 | 95.1         | 94.7          | 95.5       | 95.1         | 0.985   |
| MobileNetV2    | 89.4         | 88.6          | 90.1       | 89.3         | 0.954   |

**Table 4.** Impact of Data Augmentation Strategies (ResNet50, Hybrid Training)

| Augmentation Strategy      | Accuracy (%) | F1-Score (%) |
|----------------------------|--------------|--------------|
| No augmentation            | 91.2         | 91.0         |
| Geometric only             | 93.5         | 93.3         |
| Color only                 | 92.8         | 92.6         |
| Quality degradation only   | 94.1         | 94.0         |
| All augmentations combined | 97.0         | 97.0         |

**Table 5.** Effect of OCR Integration on System Performance.

| Verification Method     | Accuracy (%) | Precision (%) | Recall (%) | F1-Score (%) |
|-------------------------|--------------|---------------|------------|--------------|
| CNN only                | 97.0         | 96.8          | 97.2       | 97.0         |
| OCR only                | 89.3         | 88.1          | 90.4       | 89.2         |
| CNN + OCR (Multi-modal) | 98.2         | 98.1          | 98.3       | 98.2         |

**Table 6.** Inference Time Across Deployment Platforms.

| Model          | GPU (ms) | CPU (ms) | Mobile (ms) |
|----------------|----------|----------|-------------|
| ResNet50       | 12       | 187      | 342         |
| InceptionV3    | 14       | 203      | 378         |
| VGG16          | 18       | 289      | 521         |
| EfficientNetB0 | 8        | 124      | 218         |
| MobileNetV2    | 6        | 98       | 176         |

The hybrid dataset comprised 5,140 images, combining authentic samples with both real and synthetic counterfeit images. Across all architectures, hybrid training consistently outperformed real-only and

synthetic-only training. ResNet50 achieved the highest performance with 97.0% accuracy, 97.2% recall, and an AUC-ROC of 0.993. Compared to real-only training, hybrid training improved accuracy by 4.7%, while reducing overfitting as evidenced by smoother learning curves and lower validation loss.

Synthetic-only training produced respectable results but lagged behind real and hybrid approaches, indicating that synthetic images alone cannot fully capture real-world variability. Ablation studies showed that combined augmentation strategies yielded a 5.8% accuracy improvement over no augmentation. OCR integration further increased overall system accuracy to 98.2% and reduced false negatives by 41% relative to image-only classification.

Cross-dataset evaluation on unseen pharmaceutical products demonstrated strong generalization, with accuracy remaining above 92%. Mobile deployment experiments showed that a quantized ResNet50 model achieved 176 ms inference time on a Snapdragon 888 device with minimal accuracy loss, confirming suitability for real-time use.

## Discussion of Findings

The results presented in Tables 1–6 provide strong empirical support for the effectiveness of the proposed hybrid deep learning framework. As shown in Table 1, models trained exclusively on real-world pharmaceutical images achieved moderate to high accuracy, with ResNet50 outperforming other architectures at 92.3%. This aligns with prior studies that report strong performance of residual networks in fine-grained visual classification tasks due to their ability to preserve low-level feature representations through skip connections [12].

However, Table 2 demonstrates that training on synthetic data alone leads to a noticeable reduction in performance across all models, with accuracies dropping by approximately 7–10% relative to real-only training. Similar observations have been reported in related works where synthetic images, while visually realistic, fail to fully capture uncontrolled environmental factors such as lighting variability, camera noise, and real-world packaging wear [21]. These findings confirm that synthetic data alone is insufficient for robust counterfeit detection.

The most significant insight emerges from the hybrid training results summarized in Table 3. All architectures benefit substantially from the inclusion of synthetic data alongside real samples, with ResNet50 achieving a peak accuracy of 97.0% and an AUC-ROC of 0.993. Compared to the real-only baseline in Table 1, this represents a 4.7% absolute improvement in accuracy. This result exceeds the performance reported in earlier vision-based counterfeit drug detection studies, which typically achieve accuracies in the range of 90–94% using limited real datasets [17-18]. The findings are consistent with recent literature in medical imaging and industrial inspection, where hybrid datasets have been shown to improve generalization and reduce overfitting [22]

Table 4 further highlights the importance of comprehensive data augmentation. The combined augmentation strategy yields a 5.8% improvement in accuracy over no augmentation, reinforcing claims in

related work that robustness to geometric distortions and image degradation is critical for real-world deployment. Studies using only basic augmentation techniques have reported smaller gains, indicating that the richer augmentation pipeline adopted here provides a competitive advantage [22-23].

The impact of integrating textual verification is evident in Table 5. While OCR alone performs poorly relative to CNN-based image classification, the combined CNN + OCR approach achieves the highest overall accuracy of 98.2% and significantly reduces false negatives. This finding is consistent with prior multi-modal authentication systems that combine visual inspection with serial number or text verification, although many earlier approaches rely on proprietary databases or blockchain infrastructure [24-25]. In contrast, the proposed system achieves comparable or superior accuracy using only on-device computation.

Finally, Table 6 demonstrates the practicality of the approach for real-world use. Lightweight architectures such as MobileNetV2 and EfficientNetB0 offer faster inference times on mobile devices, but at the cost of reduced accuracy relative to ResNet50. This trade-off mirrors observations in related mobile health applications, where model selection depends on balancing computational constraints against classification reliability. The quantized ResNet50 results indicate that high accuracy can still be achieved within acceptable latency bounds, supporting deployment in low-resource settings.

Overall, when compared with related works in counterfeit drug detection, the proposed hybrid framework delivers superior accuracy, stronger generalization, and improved practicality, largely due to the synergistic use of diffusion-based synthetic data, extensive augmentation, and multi-modal verification. The results demonstrate that hybrid training leverages the complementary strengths of real and synthetic data. Real images capture authentic environmental conditions, while synthetic images provide controlled diversity in counterfeit characteristics and mitigate class imbalance. The superior performance of ResNet50 highlights the importance of deep residual architectures for capturing subtle visual cues in pharmaceutical packaging. The modest yet meaningful improvement from OCR integration underscores the value of multi-modal verification, particularly in cases where counterfeit drugs closely mimic authentic visual appearance but contain textual errors. Compared with prior work, the proposed approach achieves higher accuracy while requiring only smartphone hardware, enhancing accessibility in resource-constrained settings.

### ***Practical Implications and Limitations***

The proposed system is suitable as a screening tool for pharmacists, healthcare workers, and regulators, particularly in regions with high counterfeit prevalence. However, it is not intended to replace laboratory-based regulatory testing. Limitations include reliance on publicly available datasets and synthetic generation assumptions, which may not capture all real-world counterfeit strategies. Future work should incorporate larger proprietary datasets, explore additional modalities such as hyperspectral imaging, and investigate continual learning to adapt to evolving counterfeit techniques.

## Conclusion

This study demonstrates that synthetic data generation using diffusion models, when combined with real-world images, significantly enhances deep learning–based counterfeit drug detection. The hybrid approach achieves state-of-the-art performance, robust generalization, and practical deployability on mobile devices. These findings support the adoption of generative AI as a powerful tool for addressing data scarcity in pharmaceutical authentication and contribute toward scalable, accessible solutions for combating counterfeit medicines.

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