Low-resolution image reconstruction methodology using Generative Adversarial Network (GAN) to improve drug product quality assessment

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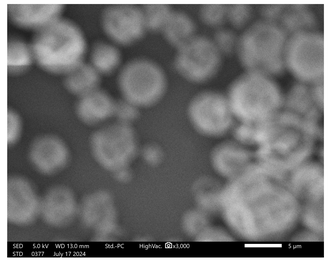
Abstract

Accurate and unbiased microstructure analysis from micrographs is crucial for thoroughly understanding the relationships between processes, microstructures, and properties, as well as for developing customized materials. However, as microstructures become more complex, advanced segmentation techniques are required. High-resolution imaging often necessitates special sample preparations and extended imaging times. In contrast, lower-resolution techniques are faster, however often present challenges in restoring fine details and textures. This project leverages generative AI to enhance microstructure inference from low resolution micrographs, aiming to provide a comprehensive understanding of process-microstructure property relations. Generative AI, particularly Generative Adversarial Networks (GANs), has demonstrated promise in generating high-resolution images from low-resolution inputs by predicting and reconstructing missing details.

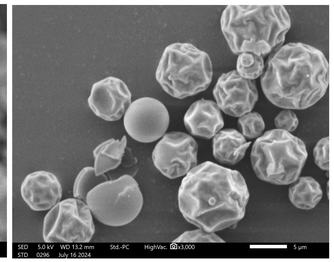
Importance of Resolution for Quality Assessment

Factors	Low Resolution	High Resolution
Image Quality	Poor, blurry, pixelated	Clear, sharp, high definition
Detail	Low detail, loose granular information, visible pixels	High detail, contain granular details, smooth edges
Storage Capacity	Can store more images	Can store fewer images
Cost	Inexpensive	Expensive
Viewing Experience	Unpleasant, hard to view	Pleasant, easy to view
File Size	Small	Large
Measurement Time	Shorter	Longer

Table: Benefits and Limitation of High- and Low- Resolution Images



(a) Low Resolution Image of Naloxone Particles



(b) High Resolution Image of Naloxone Particles

Figure: Benchtop Scanning Electron Microscope (SEM) images for low- and high- resolution images for Naloxone Sample

Methodology

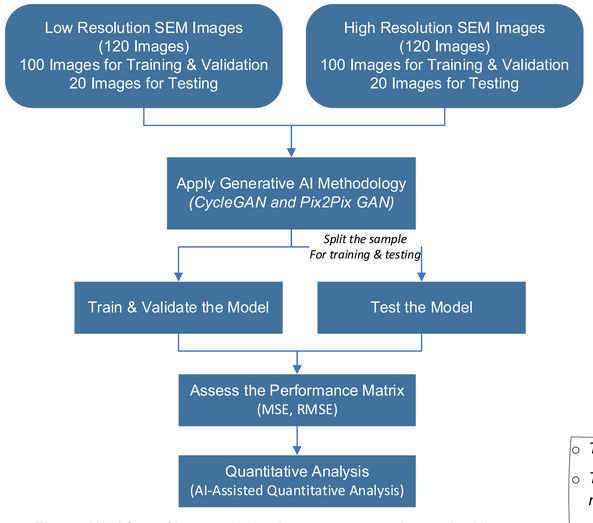
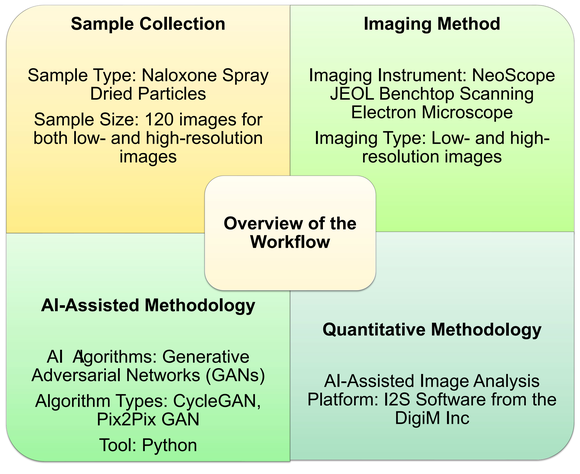
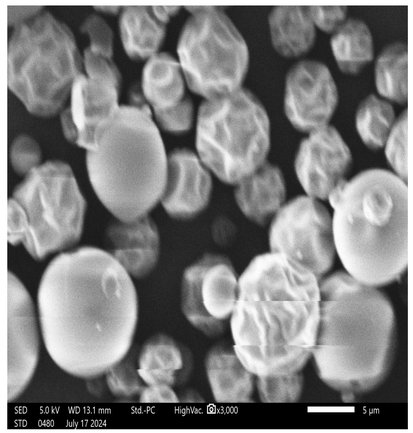


Figure: Workflow of Low-resolution image reconstruction methodology

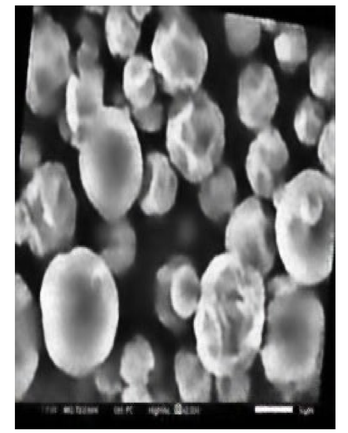


- *The GAN algorithms upscale the input image to generate the super-resolution images.*
- *The Generator and discriminator model help to classify the output given by the Generator model as real or fake.*
- *The Generator gets the feedback on loss from the Discriminator model and aims to minimize the loss.*

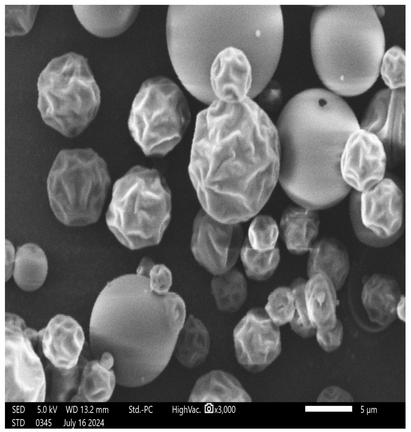
Image Reconstruction using the Generative AI : GAN



(A) Low resolution images – Input Image



(B) Generated Image from the GAN Algorithm



(C) High resolution images – Ground Truth Image

Results and Discussion

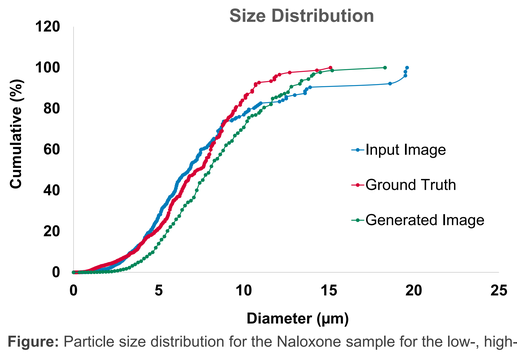
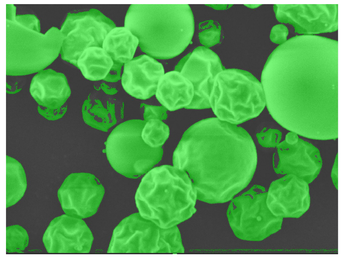


Figure: Particle size distribution for the Naloxone sample for the low-, high-, and generated- images

Performance Metrics from the GANs Outcome	
Mean Squared Error (MSE)	0.44
Root Mean Squared Error (RSME)	0.61

Disclaimer

This poster reflects the views of the authors and should not be construed to represent FDA's views or policies.



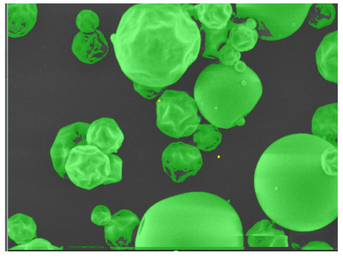


Figure: AI-assisted image analysis for quantitative analysis – segmentation of particles and background using the Image 2 Simulation (I2S) platform.

Conclusion & Regulatory Impact

- ❑ In the current sample, the difference between low- and high- resolution images are not significantly different.
- ❑ The generated image needs further improvement by running more epochs.
- ❑ Need to use more images to improve the model taining.
- ❑ This proof-of-concept study will provide rapid, high-throughput, and objective analysis.
- ❑ In addition, he obtained knowledge will be useful for developing appropriate regulatory standards to evaluate comparative key physiochemical characteristics between the reference listed drug (RLD) and a generic product for bioequivalence purpose.

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