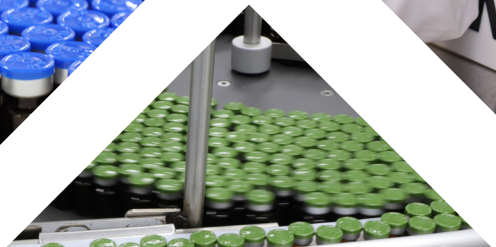
QUALITY STATEMENT

ImprimisRx® is an **FDA-Registered Outsourcing Facility** inspected by the FDA and required to meet Current Good Manufacturing Practice (cGMP) standards. We use bulk active and inactive substances obtained from FDA-registered manufacturers, accompanied by a certificate of analysis. Release and stability testing is performed at FDA-registered labs.



ImprimisRx® Quality Statement

ImprimisRx has a strong commitment to quality, safety and compliance. Over the last 4 years, ImprimisRx has invested more than 10 million dollars in our quality systems. We have a highly experienced quality team of 25 individuals, led by experienced management with extensive backgrounds in highly regulated branded pharmaceutical manufacturing and Current Good Manufacturing Practice (cGMP) standards.

Imprimis continuously works to achieve pharmaceutical-level standards and protocols consistent with what is required in compounding for all products and processes within the 503A pharmacy and FDA-Registered 503B Outsourcing Facility. The quality control for analytical and stability testing is performed using an FDA-Registered in-house Current Good Laboratory Practices (CGLP) laboratory with outside support from FDA-Registered labs. Additionally, Imprimis utilizes the Lighthouse Monitoring System to continuously monitor and display critical environmental data used in pharmaceutical manufacturing.

Imprimis utilizes electronic batch records to verify each step in the manufacturing process to eliminate human error and ensure each step has been carried out according to cGMP standards. Imprimis has implemented the Veeva Electronic Quality Management system, a cloud-based software designed to streamline quality processes within a united platform.

Imprimis Key Quality Metrics Include:

- Meeting FDA ranges for Quality to Manufacturing personnel ratio of 17% to 24%.
- Surface and air testing for viable and non-viable particulates is performed in our 503B facility 5,876 times a week.
- 24-hour product temperature and humidity monitoring.
- Production cleanrooms are cleaned and sanitized daily.
- Independent cleanroom certifications and media fills are performed every 6 months.
- Vaporized hydrogen peroxide (VHP) sterilization in all ISO areas every three months.
- Smoke studies are performed annually.
- Any serious and or unexpected adverse events are reported to the FDA within 15 days as per FDA regulations.

Imprimis NJOF has undergone over 21 audits over the past seven years by regulatory authorities including the Food and Drug Administration, Drug Enforcement Administration, New Jersey State Board of Pharmacy, California Board of Pharmacy, Nevada Board of Pharmacy, The National Association of Boards of Pharmacy and seven audits conducted by highly respected auditing firms including: Lachman Consulting Services, Gates Healthcare and Bestech GMP Contracting. These audits were comprehensive and included evaluation of critical quality and production systems including:

Documentation Control System	Pharmacist Oversite	Standard Operating Procedures	Quality Management System	Complaint Handling System	Corrective and Preventive Actions
Product Development	Adverse Event Reporting	Change Control Process	Finished Product Testing	Finished Product Disposition	BUD Determination
Finished Product Specifications	Raw Materials Testing and Release	Clean room Certification	HEPA filter Certification	Laminar Flow Hood Certification	Deviation Process
Batch Record Review	cGMP Training	Technician Qualification	Sampling Processes and Plans	Retain Process	Internal Audit Process
Stability Programs	Cleaning and Sterilization Process	Aseptic Technique Assessment	Gowning Technique Qualification	Quality Attribute Parameters	Raw Materials Storage
Lot Coding System	HVAC and Environmental Control Systems	Environmental Monitoring Process	Incubation Facilities	Autoclave Process	Smoke Studies
Media Fill Simulations	Distribution Center	Packaging	Cold Storage	Shipping	Customer Service

We have seen continuous improvement with all of our inspections. Our latest 2024 FDA inspection resulted in only 5 observations and no repeat observations from any previous FDA inspections.

Our Quality Unit has evolved steadily into a compliance-driven department, supporting an ever-increasing mechanized production unit. The average years of industry experience in the Quality Unit is 16 years with Quality Leadership being in the industry for a combined 64 years. Our Quality Unit is comprised of individuals from all sectors of the pharmaceutical industry including Quality, Compliance, Regulatory and Production.

Imprimis NJOF believes that we possess the most technical, experienced and knowledgeable team of Quality and Production personnel in the 503B Outsourcing field. We are confident that we produce high quality drug products in the 503B industry and continue to be leaders in the Ophthalmic drug market. We welcome any of our customers to arrange a visit to our Ledgewood, NJ facility to see firsthand our state-of-the-art facility and processes.

Compounded formulations are not approved by FDA. They have not been reviewed by FDA for safety and efficacy. These formulations carry risks.

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imprimis Rx®