



Our Manufacturing

We understand the importance of manufacturing under stringent standards to create consistent, safe and scalable high-quality FMT products. Novel Biome has a Health Canada Drug Establishment Licence (DEL), and our laboratory and manufacturing space are Good Manufacturing Practices (GMP) certified and follow Good Laboratory Practices (GLP). We understand the importance of manufacturing under stringent standards to create consistent, safe, and scalable high-quality FMT products.

OUR STANDARDS

Novel Biome has spent several years perfecting the FMT manufacturing process and investing significantly to ensure safe, effective and convenient FMT products manufactured under GMP standards. Our sole focus is on FMT manufacturing and producing the best FMT products possible. We want to make our products available to a broader market to best support the growing need for this life-saving treatment.

Novel Biome provides four product formats: enema, colonoscopy, capsules and oral powder created in our specialized GMP- certified microbiota laboratory, which includes in-house finished product testing. All our FMT products are created utilizing our highly screened and vetted donor network, exceeding industry standards.

SPECIALIZED FMT MANUFACTURING

At Novel Biome, we adhere to GMP standards to ensure the quality, safety, and consistency of our FMT product. GMP is a set of guidelines established by regulatory agencies that ensure the quality, safety and efficacy of pharmaceutical and medical products, such as FMT. These guidelines cover all aspects of the manufacturing process, from raw materials screening, standard operating procedures (SOPs) and quality assurance processes to packaging and labelling of finished products.

To ensure the Quality, Safety and Consistency of our FMT products, we place the highest stands on:

- **Hiring the Very Best Lab Personnel**
- **Purchasing the Best Facility and Laboratory Equipment**
- **Ensuring our Test Systems and Processes are Optimal**
- **Exceptional Manufacturing Processes, Quality Assurance and Standard Operating Procedures**
- **Stringent Donor Screening, Blood, and Stool Testing**
- **Adverse Event Reporting**

All finished product testing is completed in-house on every batch of FMT products in our GMP-certified lab space. All products undergo environmental and finished product testing, including total probiotic count, and a CoA can be shared upon request.

Our commitment to producing high-quality products is reflected in our use of both Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) and our Health Canada Drug Establishment Licence (DEL).

OUR CUSTOM-BUILT MICROBIOME LABORATORY MANUFACTURING SPACE



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