

# Comparator Product Testing

Before a product within the same therapeutic class as another can be released to the market, comparator product testing must be performed to confirm that the product's benefits outweigh that of the current, comparable product on the market.

There are many aspects of comparator product testing including, release testing of clinical supplies/materials for manufacturing, development and validation of assay, impurity and dissolution methods, stability studies and clinical release.

Eurofins BioPharma Product Testing offers a comprehensive range of comparator product testing services to support new products in development, as well as for marketed products of the same therapeutic class. Our analysts focus on the innovator product to develop and validate methods needed to support the client's stability and clinical studies.

## Why Choose Eurofins BioPharma Product Testing?

We have extensive experience, including performing comparator product testing on more than 70 different products.

We are able to provide technical consultation related to specific challenges associated with comparator product testing.

Analysts have extensive hands-on laboratory experience with comparator products in order to provide effective and reliable technical project support.



## Testing Available

- Release testing of clinical supplies/raw materials for manufacturing
  - Packaging materials (refer to container testing fact sheet)
  - Capsule shells
  - Capsule filler material
  - API
- Development and validation of assay, impurity and dissolution methods
- Stability studies
- Clinical release

## Test Methods

- Assay/Identification (chromatographic – stability indicating)
- Related Substances (not always needed)
- Dissolution
- Moisture Content Determination (Karl Fischer)
- Microbial Limit Testing
- Residual Alcohol (deprinting)

## Experience

Eurofins BioPharma Product Testing has extensive experience performing comparator product testing on more than 70 different products, including:

- Adefovir
- Adefovir dipivoxil
- Alprazolam
- Amytriptyline
- Aripiprazole
- Atomoxetine
- Atorvastatine
- Azathioprene
- Azithromycin
- Caffeine
- Carbamazepine
- Celecoxib
- Cephalexin
- Clindamycin
- Cilostazol
- Decitabine
- Dexamethasone
- Diclofenac
- Dienogest
- Donepezil
- Duloxetine
- Escitalopram
- Estradiol
- Etoricoxib
- Ezetimibe
- Fenofibrate
- Gabapentin
- Glimepiride
- Glypizide
- Guanfacine
- Hydrocodone/APAP
- Indomethacin
- Lansoprazole
- Leflunomide
- Levorphenol
- Lorazepam
- Loxoprofen
- Loratidine
- Methotrexate
- Metformin
- Misopristol
- Mitiglinide
- Montelukast
- Morphine Sulfate
- Naltrexone
- Naproxen
- Norethindrone
- Olanzapine
- Oseltamivir
- Oxybutynin
- Oxycodone/APAP
- Paracetamol
- Paroxetine
- Phentermine
- Pimonadazole
- Pioglitazone
- Prednisone
- Pregabalin
- Pseudoephedrine
- Quetiapine
- Raloxifene
- Ribavirin
- Risedronate
- Risperidone
- Rosuvastatin
- Sibutramine
- Simvastatin
- Sitagliptin
- Sulfamethoxazole
- Tapentadol
- Topiramate
- Terbinafine
- Trimethoprim
- Valacyclovir
- Varenicline

### Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing  
Cell Banking Services • Virology Services • Facility & Process Validation  
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
Stability Testing & Storage • Primary & Secondary Package Testing

### Contact Us

North America: [BioPharmaProductTesting@BPT.EurofinsUS.com](mailto:BioPharmaProductTesting@BPT.EurofinsUS.com)  
Europe: [Information@BPT.EurofinsEU.com](mailto:Information@BPT.EurofinsEU.com)  
APAC: [easl.cserv@BPJP.EurofinsAsia.com](mailto:easl.cserv@BPJP.EurofinsAsia.com)  
[www.Eurofins.com/BPT](http://www.Eurofins.com/BPT)



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