

Because you care  
about CONSUMERS' HEALTH



## Over-The-Counter (OTC) Products

Over-the-counter (OTC) drugs are medicines sold directly to a consumer without a prescription from a healthcare professional. In the United States, the manufacture and sale of these products are regulated by Food and Drug Administration through the OTC Drugs Regulation requiring OTC drugs to be manufactured and controlled in accordance with Current Good Manufacturing Practice (cGMP).

Merieux NutriSciences provides a full range of cGMP compliant analytical services suitable for OTC drugs manufacturer and distributors. Thanks to our long-term expertise developed in the pharmaceuticals and cosmetics segments we can adequately support also non pharmaceutical companies to satisfy GMP analytical requirements applicable to OTC drugs.

In fact, several products (e.g. make up and sun protection products, toothpastes) that in EU are not strictly classified as medicines could be considered as OTC drugs in U.S.A according to their real use and other characteristics (i.e. ingredients composition, claims/publicity, perception of the public about the product).

### OTC PRODUCTS

#### Sun Protection Products

Sunscreens

Skin Care

Make-up

(products with solar protection claims)

Anti-Cavities

(e.g. toothpastes with Fluoride)

Deodorants

(with anti-perspirants claims)

Anti-dandruff

Skin Protectants

Anti-aging

Wart Removers

### SERVICES

Cleaning Validation

Methods Development & Validation

Microbiological & Physico-Chemical

Quality Controls

Challenge Tests

Stability Studies

Photostability Studies

Sample storage

USP & OTC Monographs testings

Consultancy & Regulatory support

### ADDED VALUES

Pharma & Cosmetics expertise merged together

cGMP compliant dedicated facility & LIMS

FDA inspected

>8 years of experience on

GMP testings

>16 years of experience on cosmetics testings

>3500 volunteers for safety & efficacy tests

>280m<sup>3</sup> space available in stability chambers

>500 methods available for UV filters, APIs and preservatives and impurities determination

For further information please contact our expert  
by calling **+39 04237177** or writing an email to  
**[gxp.italy@mxns.com](mailto:gxp.italy@mxns.com)**



Via Fratta 25, 31023 Resana, Italy  
tel. +39 0423 7177  
e-mail [gxp.italy@mxns.com](mailto:gxp.italy@mxns.com)

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