



CONTRACT MANUFACTURING SUPPORT SERVICES

Therapex provides the following support services to its Contract Manufacturing customers.

ANALYTICAL SERVICES

Therapex comprehensive Analytical and Quality Control laboratories support development and production requirements.

Instrumentation and capabilities include:

- HPLC
- G C
- G C Headspace
- FTIR
- Atomic absorption
- High capacity wet chemical laboratory
- Full compendia testing (USP/NF, PhEur)
- LIMS system
- Chem Store software on server

TEST METHOD DEVELOPMENT

Our scientists develop and validate new analytical methods for Drug substance, Drug product, Impurities and Degradants and Cleaning methods.

STABILITY TESTING

Therapex provides its customers with comprehensive stability programs for formulation evaluation, clinical supplies and commercial finished products including study protocols, summary reports and recommendations for shelf life. Three fully validated ICH conditions stability chambers are on site.

MICROBIOLOGY

Therapex has a fully equipped cGMP compliant microbiology laboratory. Our microbiologists perform microbial count, identification of micro organism and preservatives efficacy testing.

Our analytical and microbiology services team operate under cGMP and ICH guidelines and are compliant to US, EU and Canadian regulations.

Therapex®



REGULATORY SERVICES

Therapex has been successfully audited by FDA (no 483's) Health Canada and European Community regulatory agencies.

We offer support for NDS, NDA, ANDA, 510(k), DIN Medical Device licence and EU variation or registration.

For IND submission, Methods Development and Analytical testing teams with Regulatory team develop and prepare the technical portions of the Chemistry, Manufacturing and Controls (CMC) application.

For NDA/ANDA submission, the Methods Development and Analytical testing will develop and prepare data for the CMC section that includes: specifications and validation of test methods for drug substance and drug product, characteristics of drug substance, stability data, characterization of impurities.

VALIDATION

Therapex validation department offers complete services for equipment qualification, cleaning process and packaging validation.

THERAPEX
Your Key Partner
In Contract Manufacturing

Call 1-800-465-5820 to discuss your challenges and our creative solutions

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www.therapex.com