TERANGA GROUPE

STABILITY STUDIES AND STORAGE 1/2

Do you need to outsource you stability studies or sample storage?

CEBIPHAR offers its sophisticated technical platform and its multidisciplinary team to support your pre and post marketing studies.

Your needs :

To perform stability studies for:
- Requests for clinical studies authorisation (IND, IMPD)
- Registration files (NDA, Security Report)
- Post-marketing studies (on-going stability)

Studies for APIs, bulk products and finished products
All ICH-VICH conditions, long term, intermediary and accelerated conditions
Pre-stability studies for formulation screening
Forced degradation studies for:
- Demonstration of the stability indicating features of the methods
- Identification of the potential degradation products

Freezing/defrosting cycles
Photostability studies
Support studies for transport conditions

Our services: stability studies or storage only

Development and validation of stability indicating methods
Design of stability studies protocols (bracketing, matrixing) – protocols are reviewed by our Regulatory Affairs Unit
Storage in climatic chambers and samples management
Samples analysis and management of OOS/OOT

Our assets

Continuous operation & optimal protection of samples

24/7 recording and monitoring system
Qualified back-up chambers
Power generating unit
Several levels of independent security systems
Automatic protection of samples in the event of dysfunction
Internal maintenance with storage of spare parts

Our expertise

Highly qualified analysts
More than 38 years experience
Support from our technical & regulatory department

Our quality system

GMP compliant pharmaceutical site (ANSM & ANSES), FDA inspected
Studies audited by our QA department
Internal metrology & validation department

CEBIPHAR

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TERANGA GROUPE

STABILITY STUDIES AND STORAGE 2/2

Our stability storage infrastructure

Storage capacity = 140m3

ICH-VICH, WHO, ASEAN conditions for climatic zones I, II, III and IV

- 25 ± 2°C and 60 ± 5% RH: 3 chambers (16, 20 & 34 m^3)
- 30 ± 2°C and 65 ± 5% RH: 1 chamber of 21 m^3 + 4 chambers of 1300 L
- 30 ± 2°C and 75 ± 5% RH: 1 chamber of 20 m^3
- 40 ± 2°C and 75 ± 5% RH: 1 chamber of 12 m^3
- 25 ± 2°C and 40 ± 5% RH: 1 chamber of 2000 L
- 40 ± 2°C and <25% RH: 1 chamber of 2000 L
- 50 ± 2°C: 1 chamber of 100 L and 1 safety chamber
- 5 ± 3°C: 1 chamber of 5 m^3 (doubled regulation system)
- -20 ± 5°C: 1 chamber

Photostability conditions (ICH Q1B & VICH GL5)

- 1 cabinet of 1300 L
- Visible : 1,2 millions lux.hours
- UV : 200 watts.hours/m^2
- 25 ± 2°C

Other conditions

-80°C: 1 deep-freezer

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