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ll pharmaceutical development activities require thorough stability considerations. Our range of storage capabilities are fully compliant with ICH guidelines.

Stability testing

- ◆ APIs
- ◆ Finished products
- ◆ R & D preliminary stability
- ◆ Data trending
- ◆ Expiration dating
- ◆ Stability reports

Stability Storage

Galenicas stability storage conditions are in accordance with ICH guidelines. Each stability cabinet operates independently with its own temperature and humidity controls.

ALL STORAGE CHAMBERS are continuously monitored by a recorder and a computerized logg/control system.

Temperature Control/Ambient:

-20°C ± 5°C (freezer) and 5°C ± 3°C (refrigerated)

Temperature/Humidity Controls: ICH Conditions:

25°C/60%RH

30°C/65%RH

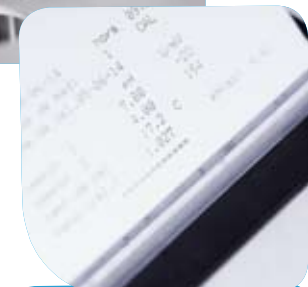
40°C/75%RH

Chamber Qualifications:

Yokogawa Instrument Stability Monitoring System

(Out of range alarms and notification)

Hardwired Security System, BAS2



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GALENICA

IT'S TIME TO FORMULATE

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