

# PSC (의약품 안정성 챔버)

# Controlled Environment

## Application



의약품 안정성 시험기는 ICH 가이드라인에 따른 신 물질과 신의약품의 안정성시험 Q1A(R2)와 화장품 안정성 시험이 가능합니다 (장기, 중간, 가속, 보관시험 가능)

## Features

- ▷ 프로그램 디지털 PID 컨트롤러를 채용하여 챔버 내부의 온도/습도 환경을 제공합니다
- ▷ 장기간 모니터링을 위한 2중 데이터 백업 장치 (옵션)를 내장하여 온도/습도의 변동 곡선을 기록
- ▷ 대용량 급수 탱크 또는 자동 급수 조절 장치는 급수에 따른 불편함을 해소합니다
- ▷ 운전 중 이상이 발생하면 시각적 청각적 알람 경고, 조절 가능한 과열 방지 장치가 내장되어 있습니다 (DIN 12880:2007-05, Thermal safety device Class 3.3)



Pharmaceutical Stability Chamber (PSC),  
Data tracing (Validation)

### \*\*\*PSC Application for stability testing in accordance with ICH Q1A(R2) harmonized tripartite guidelines;

The PSC stability chamber is capable of controlling a wide range of temperature and humidity conditions. The unit has been optimized only and validated to comply with the ICH Q1A stability guideline test conditions set out below;

#### 2.1.7.1. General case

| Study                      | Temperature    | Deviation | Humidity        | Deviation | Minimum time period covered by data at submission |
|----------------------------|----------------|-----------|-----------------|-----------|---|
| <sup>1)</sup> Long-term    | 25 °C or 30 °C | ±2 °C     | 60%RH or 65% RH | ±5% RH    | 12 months   |
| <sup>2)</sup> Intermediate | 30 °C          | ±2 °C     | 65% RH          | ±5% RH    | 6 months  |
| Accelerated                | 40 °C          | ±2 °C     | 75% RH          | ±5% RH    | 6 months  |

- 1) It is up to the applicant to decide whether long term stability studies are performed at 25 °C ±2 °C / 60% RH ±5% RH or 30 °C ±2 °C / 65% RH ±5% RH.
- 2) If 30 °C ±2 °C / 65% RH ±5% RH is the long-term condition, there is no intermediate condition.

#### 2.1.7.2. Drug substances intended for storage in a refrigerator

| Study                   | Temperature | Deviation | Humidity | Deviation | Minimum time period covered by data at submission |
|-------------------------|-------------|-----------|----------|-----------|---|
| <sup>3)</sup> Long-term | 5 °C        | ±3°C      | N/A      | N/A       | 12 months   |
| Accelerated             | 25 °C       | ±2°C      | 60% RH   | ±5% RH    | 6 months  |

- 3) Additionally a temperature only cold storage condition of +4 °C specified in the guidelines is also achievable.

#### 2.1.7.3. Drug substances intended for storage in a freezer (Please refer to Lab freezer of the thermal processing section)

| Study     | Temperature | Deviation | Humidity | Deviation | Minimum time period covered by data at submission |
|-----------|-------------|-----------|----------|-----------|---|
| Long-term | -20 °C      | ±5 °C     | N/A      | N/A       | 12 months   |

- 2.1.7.4. Drug substances intended for storage below -20 °C; Drug substances intended for storage below -20 °C should be treated on a case-by case basis.

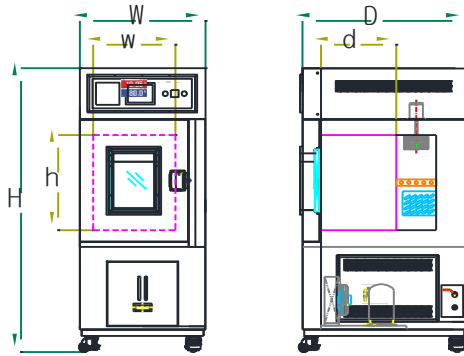


Pharmaceutical Stability Chamber **DK-Q1A150**



Pharmaceutical Stability Chamber **DK-Q1A288**

## Ordering Info.



\*\*PSC Slim body type, Dimensions **DK-Q1A150**

### Ordering No. (주문 시 선택 조합) :

**DK-Q1 A 150 D** (기타 옵션 : 밸리데이션 IQ/OQ/PQ)

- └─ **D** : Direct water supply
- └─ **B** : **150 / 316 / 765** : Chamber volume (L)
- └─ **A** : ICH Q1A

## Controller & Others



Touch screen programmable temp. & humidity controller **TEMI1500** (Option)



Paper recorder **SR10000**



Mobile alarm system **RN17x Series** & **RADIONODE365 Web** (Option)



Lime removal filter **DK-LIME**

## Specifications

| Model No.                               | DK-Q1A150  | DK-Q1A316  |                             | DK-Q1A765                    |
|---|--|--|-----------------------------|------------------------------|
| Type                                    | Slim body type   |  | General type                | Slim body type               |
| **Dimensions, w x d x h / mm (In)       | 500 x 500 x 600, 150 Liters  | 750 x 650 x 650, 316 Liters                        | 750 x 650 x 650, 316 Liters | 750 x 880 x 1160, 765 Liters |
| (Out)                                   | 1130 x 985 x 1520  | 1130 x 985 x 1520                                  | 1130 x 985 x 1520           | 1220 x 880 x 1160            |
| Controller                              | LCD Programmable digital PID control with auto tuning function <b>BK-3</b>   |  |                             |                              |
| *Temperature                            | Range  | -5 °C ~ 85 °C / Indicated in 0.1°C (Resolution)    |                             |                              |
|   | Stability  | ≤±0.3 °C ~ ≤2.0 °C @25 °C ~ 40 °C, 60% RH ~ 75% RH |                             |                              |
|   | Homogeneity  | ≤±0.5 °C ~ ≤2.0 °C @25 °C                          |                             |                              |
| *Humidity                               | Range  | 20 % ~ 90 % RH (Using 35 % ~ 85 % RH)              |                             |                              |
|   | Temporal fluctuation   | ≤±1.0 % RH ~ ≤±5.0 % RH                            |                             |                              |
| Material (In)                           | Stainless Steel (STS 304)  |  |                             |                              |
|   | (Out)  | Powder Coated Steel (SCP-1)                        |                             |                              |
| Door                                    | Silicone packing door with Observation window  |  |                             |                              |
| Refrigeration system                    | Hermetic air cooled compressor / Auto exchange dual evaporator   |  |                             |                              |
| Humidifier                              | Evaporation by motor with SUS316 pipe heater   |  |                             |                              |
| Shelf (Adjustable position), Load 30 kg | 3 ea   |  |                             | 5 ea                         |
| Safety device                           | Hydraulic thermostat (*Thermal safety device Class 3.3 TWW), Water level monitor, Power breaker, Visible & audible alarm, etc. |  |                             |                              |
| Power source (220 VAC, 60 Hz, 1 Phase)  | 4.5 kW   | 5 kW   | 6 kW                        | 7 kW                         |
| Optional Accessories                    |  |  |                             |                              |
| Controller                              | Touch screen programmable temp. & humidity controller <b>TEMI1500, TEMI2500, NEX1200, TH510</b>                                |  |                             |                              |
| Recorder                                | Digital recorder <b>DX100P, SDR100F</b> / Chart recorder <b>SR10000</b>  |  |                             |                              |
| Direct water supply                     | Lime removal filter <b>DK-LIME</b> , Bracket, Tube, Cock   |  |                             |                              |

\*In accordance with DIN 12880:2007-05, IEC 60068-3-5/6

\*\*\* ICH Q1A (R2) Guideline (2.17.1. General case & etc.)

주) 본 카탈로그의 사진, 내용 및 사양은 성능 및 품질개선을 위하여 예고 없이 변경될 수 있습니다.