

*Stability testing of active pharmaceutical ingredients  
and finished pharmaceutical products*

# Stability conditions for WHO Member States by Region<sup>1</sup>

Update March 2021



| MEMBER STATE                                     | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|--------------------------------------------------|--------------------------------------------------------------|
| Regional Office for Africa (AFRO)                |                                                              |
| <a href="#">Algeria</a>                          | [25 °C/60% RH] <sup>3</sup>                                  |
| <a href="#">Angola</a>                           | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Benin</a>                            | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Botswana</a>                         | 30 °C/50% RH <sup>1</sup>                                    |
| <a href="#">Burkina Faso</a>                     | 30 °C/60% RH <sup>2</sup>                                    |
| <a href="#">Burundi</a>                          | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Cameroon</a>                         | 30 °C/75% RH <sup>2</sup>                                    |
| <a href="#">Cape Verde</a>                       | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Central African Republic</a>         | 30 °C/75% RH <sup>2</sup>                                    |
| <a href="#">Chad</a>                             | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Comoros</a>                          | [30 °C/80% RH] <sup>1</sup>                                  |
| <a href="#">Congo</a>                            | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Côte d'Ivoire</a>                    | [30 °C/65% RH] <sup>3</sup>                                  |
| <a href="#">Democratic Republic of the Congo</a> | [30 °C/65% RH] <sup>3</sup>                                  |

<sup>1</sup> Previously included as Table 2 in *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* (Annex 2 to WHO Technical Report Series, No. 953)

| MEMBER STATE                       | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|------------------------------------|--------------------------------------------------------------|
| <u>Equatorial Guinea</u>           | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Eritrea</u>                     | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Ethiopia</u>                    | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Gabon</u>                       | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Gambia</u>                      | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Ghana</u>                       | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Guinea</u>                      | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Guinea-Bissau</u>               | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Kenya</u>                       | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Lesotho</u>                     | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Liberia</u>                     | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Madagascar</u>                  | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Malawi</u>                      | 25 °C/60% RH <sup>2</sup>                                    |
| <u>Mali</u>                        | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Mauritania</u>                  | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Mauritius</u>                   | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Mozambique</u>                  | 30 °C/75% RH <sup>1</sup>                                    |
| <u>Namibia</u>                     | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Niger</u>                       | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Nigeria</u>                     | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Rwanda</u>                      | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Sao Tome and Principe</u>       | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Senegal</u>                     | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Seychelles</u>                  | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Sierra Leone</u>                | 30 °C/75% RH <sup>2</sup>                                    |
| <u>South Africa</u>                | 25 °C/60% RH <sup>1</sup>                                    |
| <u>Swaziland</u>                   | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Togo</u>                        | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Uganda</u>                      | 30 °C/65% RH <sup>1</sup>                                    |
| <u>United Republic of Tanzania</u> | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Zambia</u>                      | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Zimbabwe</u>                    | 30 °C/75% RH <sup>2</sup>                                    |

| Regional Office for the Americas (AMRO) |                                             |
|-----------------------------------------|---------------------------------------------|
| <u>Antigua and Barbuda</u>              | [30 °C/75% RH] <sup>3</sup>                 |
| <u>Argentina</u>                        | 25 °C/60% RH <sup>2</sup>                   |
| <u>Bahamas</u>                          | [30 °C/65% RH] <sup>3</sup>                 |
| <u>Barbados</u>                         | 30 °C/75% RH <sup>2</sup>                   |
| <u>Belize</u>                           | [30 °C/65% RH] <sup>3</sup>                 |
| <u>Bolivia</u>                          | [30 °C/70% RH or 30 °C/75% RH] <sup>3</sup> |

| MEMBER STATE                              | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|-------------------------------------------|--------------------------------------------------------------|
| <u>Brazil</u>                             | 30 °C/75% RH <sup>1</sup>                                    |
| <u>Canada</u>                             | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Chile</u>                              | 25 °C/60% RH <sup>1</sup>                                    |
| <u>Colombia</u>                           | [30 °C/75% RH] <sup>3</sup>                                  |
| <u>Costa Rica</u>                         | 30 °C/65% RH <sup>2</sup>                                    |
| <u>Cuba</u>                               | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Dominica</u>                           | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Dominican Republic</u>                 | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Ecuador</u>                            | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>El Salvador</u>                        | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Grenada</u>                            | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Guatemala</u>                          | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Guyana</u>                             | [30 °C/70% RH or 30 °C/75% RH] <sup>3</sup>                  |
| <u>Haiti</u>                              | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Honduras</u>                           | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Jamaica</u>                            | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Mexico</u>                             | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Nicaragua</u>                          | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Panama</u>                             | [30 °C/75% RH] <sup>3</sup>                                  |
| <u>Paraguay</u>                           | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Peru</u>                               | 30 °C/75% RH <sup>1</sup>                                    |
| <u>Saint Kitts and Nevis</u>              | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>Saint Lucia</u>                        | 30 °C/75% RH <sup>2</sup>                                    |
| <u>Saint Vincent and the Grenadines</u>   | [30 °C/75% RH] <sup>3</sup>                                  |
| <u>Suriname</u>                           | [30 °C/70% RH or 30 °C/75% RH] <sup>3</sup>                  |
| <u>Trinidad and Tobago</u>                | [30 °C/65% RH] <sup>3</sup>                                  |
| <u>United States of America</u>           | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Uruguay</u>                            | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Venezuela (Bolivarian Republic of)</u> | [30 °C/70% RH or 30 °C/75% RH] <sup>3</sup>                  |

| Regional Office for the Eastern Mediterranean (EMRO) |                           |
|------------------------------------------------------|---------------------------|
| <u>Afghanistan</u>                                   | 30 °C/65% RH <sup>1</sup> |
| <u>Bahrain</u>                                       | 30 °C/65% RH <sup>1</sup> |
| <u>Djibouti</u>                                      | 30 °C/65% RH <sup>1</sup> |
| <u>Egypt</u>                                         | 30 °C/65% RH <sup>1</sup> |
| <u>Iran (Islamic Republic of)</u>                    | 30 °C/65% RH <sup>1</sup> |
| <u>Iraq</u>                                          | 30 °C/35% RH <sup>1</sup> |
| <u>Jordan</u>                                        | 30 °C/65% RH <sup>1</sup> |
| <u>Kuwait</u>                                        | 30 °C/65% RH <sup>1</sup> |
| <u>Lebanon</u>                                       | 25 °C/60% RH <sup>1</sup> |

| MEMBER STATE                  | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|-------------------------------|--------------------------------------------------------------|
| <u>Libyan Arab Jamahiriya</u> | 25 °C/60% RH <sup>1</sup>                                    |
| <u>Morocco</u>                | 25 °C/60% RH <sup>1</sup>                                    |
| <u>Oman</u>                   | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Pakistan</u>               | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Qatar</u>                  | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Saudi Arabia</u>           | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Somalia</u>                | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Sudan</u>                  | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Syrian Arab Republic</u>   | 25 °C/60% RH <sup>1</sup>                                    |
| <u>Tunisia</u>                | 25 °C/60% RH <sup>1</sup>                                    |
| <u>United Arab Emirates</u>   | 30 °C/65% RH <sup>1</sup>                                    |
| <u>Yemen</u>                  | 30 °C/65% RH <sup>1</sup>                                    |

| Regional Office for Europe (EURO) |                                           |
|-----------------------------------|-------------------------------------------|
| <u>Albania</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Andorra</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Armenia</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Austria</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Azerbaijan</u>                 | 25 °C/60% RH <sup>1</sup>                 |
| <u>Belarus</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Belgium</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Bosnia and Herzegovina</u>     | [25 °C/60% RH] <sup>3</sup>               |
| <u>Bulgaria</u>                   | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Croatia</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Cyprus</u>                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Czech Republic</u>             | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Denmark</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Estonia</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Finland</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>France</u>                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Georgia</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Germany</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Greece</u>                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Hungary</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Iceland</u>                    | [25 °C/60% RH] <sup>3</sup>               |
| <u>Ireland</u>                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Israel</u>                     | 30 °C/70% RH or 30 °C/75% RH <sup>1</sup> |
| <u>Italy</u>                      | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Kazakhstan</u>                 | [25 °C/60% RH] <sup>3</sup>               |
| <u>Kyrgyzstan</u>                 | [25 °C/60% RH] <sup>3</sup>               |
| <u>Latvia</u>                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |
| <u>Lithuania</u>                  | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup> |

| MEMBER STATE                                     | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|--------------------------------------------------|--------------------------------------------------------------|
| <u>Luxembourg</u>                                | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Malta</u>                                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Monaco</u>                                    | 25 °C/60% RH or 30 °C/65% RH <sup>2</sup>                    |
| <u>Montenegro</u>                                | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Netherlands</u>                               | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Norway</u>                                    | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Poland</u>                                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Portugal</u>                                  | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Republic of Moldova</u>                       | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Romania</u>                                   | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Russian Federation</u>                        | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>San Marino</u>                                | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Serbia</u>                                    | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Slovakia</u>                                  | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Slovenia</u>                                  | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Spain</u>                                     | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Sweden</u>                                    | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Switzerland</u>                               | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Tajikistan</u>                                | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>The former Yugoslav Republic of Macedonia</u> | 25 °C/60% RH or 30 °C/65% RH <sup>2</sup>                    |
| <u>Turkey</u>                                    | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Turkmenistan</u>                              | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>Ukraine</u>                                   | [25 °C/60% RH] <sup>3</sup>                                  |
| <u>United Kingdom</u>                            | 25 °C/60% RH or 30 °C/65% RH <sup>1</sup>                    |
| <u>Uzbekistan</u>                                | [25 °C/60% RH] <sup>3</sup>                                  |

| Regional Office for South-East Asia (SEARO)  |                             |
|----------------------------------------------|-----------------------------|
| <u>Bangladesh</u>                            | [30 °C/65% RH] <sup>3</sup> |
| <u>Bhutan</u>                                | 30 °C/65% RH <sup>2</sup>   |
| <u>Democratic People's Republic of Korea</u> | [25 °C/60% RH] <sup>3</sup> |
| <u>India</u>                                 | 30 °C/70% RH <sup>1</sup>   |
| <u>Indonesia</u>                             | 30 °C/75% RH <sup>1</sup>   |
| <u>Maldives</u>                              | [30 °C/65% RH] <sup>3</sup> |
| <u>Myanmar</u>                               | 30 °C/75% RH <sup>1</sup>   |
| <u>Nepal</u>                                 | 30 °C/75% RH <sup>2</sup>   |
| <u>Sri Lanka</u>                             | [30 °C/65% RH] <sup>3</sup> |
| <u>Thailand</u>                              | 30 °C/75% RH <sup>1</sup>   |
| <u>Timor-Leste</u>                           | [30 °C/65% RH] <sup>3</sup> |

| Regional Office for the Western Pacific (WPRO) |
|------------------------------------------------|
|------------------------------------------------|

| MEMBER STATE                            | STABILITY CONDITIONS<br>CONFIRMED LONG-TERM TESTING ONDITION |
|-----------------------------------------|--------------------------------------------------------------|
| <u>Australia</u>                        | 25 °C/60% RH or 30 °C/65% RH <sup>2</sup>                    |
| <u>Brunei Darussalam</u>                | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>Cambodia</u>                         | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>China</u>                            | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Cook Islands</u>                     | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Fiji</u>                             | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Japan</u>                            | <b>25 °C/60% RH or 30 °C/65% RH<sup>1</sup></b>              |
| <u>Kiribati</u>                         | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Lao People's Democratic Republic</u> | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>Malaysia</u>                         | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>Marshall Islands</u>                 | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Micronesia (Federated States of)</u> | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Mongolia</u>                         | <b>[25 °C/60% RH]<sup>3</sup></b>                            |
| <u>Nauru</u>                            | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>New Zealand</u>                      | 25 °C/60% RH or 30 °C/65% RH <sup>2</sup>                    |
| <u>Niue</u>                             | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Palau</u>                            | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Papua New Guinea</u>                 | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Philippines</u>                      | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>Republic of Korea</u>                | 25 °C/60% RH or 30 °C/65% RH <sup>2</sup>                    |
| <u>Samoa</u>                            | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Singapore</u>                        | <b>30 °C/75% RH<sup>1</sup></b>                              |
| <u>Solomon Islands</u>                  | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Tonga</u>                            | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Tuvalu</u>                           | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Vanuatu</u>                          | <b>[30 °C/65% RH]<sup>3</sup></b>                            |
| <u>Viet Nam</u>                         | <b>30 °C/75% RH<sup>1</sup></b>                              |

<sup>1</sup> Information obtained through respective regional harmonization groups (e.g. ASEAN, ICH and GCC) and from official communications from national medicines regulatory authorities to WHO (entries in bold type).

<sup>2</sup> Information collated during the 13th International Conference of Drug Regulatory Authorities (ICDRA), 16–18 September 2008, held in Berne Switzerland, from representatives of national medicines regulatory authorities (entries in normal type).

<sup>3</sup> Information provided by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) [entries in italic type] based on the following references:

- Ahrens CD. 2001. *Essentials of meteorology* 3rd ed. Belmont, CA, Thomson Books/Cole, p. 433.

- Kottek M, et al. 2006. World Map of Köppen-Geiger Climate Classification updated. *Meteorologische Zeitschrift*, 15:259–263.

- Zahn M. et al. 2006. A risk-based approach to establish stability testing conditions for tropical countries. *Journal of Pharmaceutical Sciences*, 95:946–965. Erratum *Journal of Pharmaceutical Sciences*, 2007, 96:2177.
- Zahn M. 2008. Global stability practices. In: Huynh-Ba, Kim ed. *Handbook of stability testing in pharmaceutical development*, New York, Springer.