

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

Stability conditions for WHO Member States by Region¹

Update March 2021



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

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

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

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

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

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

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

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

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

Regional Office for the Western Pacific (WPRO)
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MEMBER STATE	STABILITY CONDITIONS CONFIRMED LONG-TERM TESTING ONDITION
<u>Australia</u>	25 °C/60% RH or 30 °C/65% RH ²
<u>Brunei Darussalam</u>	30 °C/75% RH¹
<u>Cambodia</u>	30 °C/75% RH¹
<u>China</u>	<i>[30 °C/65% RH]³</i>
<u>Cook Islands</u>	<i>[30 °C/65% RH]³</i>
<u>Fiji</u>	<i>[30 °C/65% RH]³</i>
<u>Japan</u>	25 °C/60% RH or 30 °C/65% RH¹
<u>Kiribati</u>	<i>[30 °C/65% RH]³</i>
<u>Lao People's Democratic Republic</u>	30 °C/75% RH¹
<u>Malaysia</u>	30 °C/75% RH¹
<u>Marshall Islands</u>	<i>[30 °C/65% RH]³</i>
<u>Micronesia (Federated States of)</u>	<i>[30 °C/65% RH]³</i>
<u>Mongolia</u>	<i>[25 °C/60% RH]³</i>
<u>Nauru</u>	<i>[30 °C/65% RH]³</i>
<u>New Zealand</u>	25 °C/60% RH or 30 °C/65% RH ²
<u>Niue</u>	<i>[30 °C/65% RH]³</i>
<u>Palau</u>	<i>[30 °C/65% RH]³</i>
<u>Papua New Guinea</u>	<i>[30 °C/65% RH]³</i>
<u>Philippines</u>	30 °C/75% RH¹
<u>Republic of Korea</u>	25 °C/60% RH or 30 °C/65% RH ²
<u>Samoa</u>	<i>[30 °C/65% RH]³</i>
<u>Singapore</u>	30 °C/75% RH¹
<u>Solomon Islands</u>	<i>[30 °C/65% RH]³</i>
<u>Tonga</u>	<i>[30 °C/65% RH]³</i>
<u>Tuvalu</u>	<i>[30 °C/65% RH]³</i>
<u>Vanuatu</u>	<i>[30 °C/65% RH]³</i>
<u>Viet Nam</u>	30 °C/75% RH¹

¹ 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).

² 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).

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

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