

Section Guidance for Part 5 Labelling of a WHO Public Assessment Report (WHOPAR)

1. SECTION 9 (SPECIAL STORAGE CONDITIONS)

The Labelling document is submitted by the applicant when submitting a finished pharmaceutical product to WHO for prequalification. After evaluation by the assessment team it will be included as Part 5 of the WHO Public Assessment Report that will be posted on the WHO medicines prequalification website, should the product attain prequalification.

The Labelling document should include a description of any special storage conditions as Section 9: Special storage conditions. Suggested content for this section is given below. <text> signifies text to be selected or deleted as appropriate while {text} refers to information to be added.

<Do not store above <25 °C> <30 °C>> or

<Store below <25 °C> <30 °C>>

<Store in a refrigerator>

<Store and transport refrigerated>*

<Store in a freezer>

<Store and transport frozen>**

<Do not <refrigerate> <or> <freeze>>

<Store in the original <package>>

<Keep the {container}*** tightly closed>

<Keep the {container}*** in the outer carton>

<in order to protect from <light> <moisture>.>

See also WHO Technical Report Series, No. 970, *Guidelines on Submission of Documentation for a Multisource (Generic) Finished Pharmaceutical Product for the WHO Prequalification of Medicines Programme*. Annex 4, 2012.