SECTION 5 (STORING X)

The Patient Information Leaflet (PIL) is submitted by the applicant when submitting a finished pharmaceutical product to WHO for prequalification. After evaluation by the WHO Prequalification Team: medicines (PQTm) it will be included as Part 3 of the WHO Public Assessment Report that will be posted on PQTm’s website, should the product attain prequalification.

The PIL should include a description of any special storage conditions. The applicable storage statement(s) are determined during the quality assessment of the stability data and may include one or more of the following statements. <text> signifies text to be selected or deleted as appropriate.

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

<Avoid excursions above <30°C> <25°C>>

<Store in a refrigerator (2°C – 8°C)>

<Store and transport refrigerated (2°C – 8°C)>

<Store in a freezer {temperature range}>

<Store and transport frozen {temperature range}>

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

<Store in the original <package>>

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

<Keep the {container}²** tightly closed>

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

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¹ The stability data generated at 30°C/75%RH and 40°C/75%RH is taken into account when deciding whether excursions above <30°C> <25°C> may not be appropriate for the safe use of the medicine in climatic zones III, IVa and IVb.

² The type of the container should be stated (e.g., bottle, blister).