### 3.2.P.8 Stability *(name, dosage form)*

### 3.2.P.8.1 Stability summary and conclusion *(name, dosage form)*

A tabulated summary of the data, clearly indicating the number and types / sizes (production, pilot or experimental) of batches, packaging material, storage conditions and storage period, and manufacturer of the API with API batch numbers, should be included for each final product manufacturer.

### 3.2.P.8.2 Post-approval stability protocol and stability commitment *(name, dosage form)*

### 3.2.P.8.3 Stability data *(name, dosage form)*

All applications for registration of a medicine should be submitted with stability data in accordance with the minimum requirements stated in the Stability guideline.