

Module 1.0.1: Note to Evaluator

Product: Amoxicillin 250 mg/5 mL powder for oral suspension

Sequence: 0000

Subject: Guide to Stability Justification and ICH Q3D Compliance

1. Purpose of this Note

This note is provided to assist the evaluator in locating and reviewing the key Quality (CMC) data supporting this application, with particular focus on the remediation of legacy gaps to align the dossier with current Australian regulatory expectations.

2. Stability Strategy (Module 2.3 and Module 3.2.P.8)

The applicant acknowledges that 24-month stability data at Zone IVb (30°C /75% RH) is currently in progress.

- To support immediate registration, a **Stability Commitment** is provided in **Module 3.2.P.8.2**.
- The applicant proposes an initial **12-month shelf life**.
- Additional scientific justification for the physical and chemical robustness of the formulation, including the role of the xanthan gum suspension matrix and pH control, is presented in the Quality Overall Summary (Module 2.3.P).

3. Elemental Impurities (Module 3.2.P.5.4)

A quantitative risk assessment for elemental impurities per **ICH Q3D** has been conducted.

- Legacy qualitative data has been superseded by **ICP-MS analysis** of three (3) industrial-scale validation batches.
- The summary of results and the analytical validation report for the ICP-MS method are located in **Module 3.2.P.5.3 (Validation of Analytical Procedures)**.

4. Biowaiver Justification (Module 1.5.1)

A request for a biowaiver for in vivo bioequivalence studies is included in **Module 1.5.1**. This request is supported by comparative dissolution data across the physiological pH range (1.2, 4.5, and 6.8), which is detailed in **Module 3.2.P.2 (Pharmaceutical Development)**.