australian pharmacy council

Workplace-based assessment Tool

Entrustable professional activity (EPA) 2: Compounding pharmaceutical products Preceptor and intern user guide

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List of Abbreviations

Abbreviation	Term
APC	Australian Pharmacy Council
APF	Australian Pharmaceutical Formulary and Handbook
A RICH	Agency, Reliability, Integrity, Capability, Humility
EPA	Entrustable Professional Activity
ITA	In Training Assessment Activity
ITP	Intern Training Program
PharmBA	Pharmacy Board of Australia
PPE	Personal Protective Equipment
QUM	Quality Use of Medicines
SPO	Short Practice Observation
TGA	Therapeutic Goods Administration

Who should use this document

This document is to be used by pharmacist interns, preceptors, supervising pharmacists and Intern Training Program (ITP) providers.

This document outlines the Entrustable Professional Activity – Compounding pharmaceutical products developed by the Australian Pharmacy Council (APC) for use in the assessment of pharmacy interns in Australia.

The tool is intended to assist with the assessment of an intern's achievement of one or more of the performance outcomes listed in the Performance Outcomes Framework 2020[1] which accompanied the 2020 Accreditation Standards for Pharmacy Programs in Australia[2].

Interns will use the tool and the templates for reflecting on, and seeking feedback on their performance from their supervisor, on compounding pharmaceutical products.

Preceptors and supervising pharmacists (collectively referred to as Supervisors) will use the tool and template for assessing the intern's performance, providing feedback to the intern, and jointly formulating a plan for future development with the intern.

Intern Training Program providers will incorporate the tool into the Intern Portfolio, which is the compiled record of the intern's achievements during the intern year, and which is used as the basis for determining whether the intern has achieved many of the performance outcomes. ITP providers may choose to use the assessment of this EPA as part of the formal requirement of the ITP.

Reference documents

Familiarity with the following documents is recommended and they should be read in conjunction with this User Guide.

1. Intern pharmacist and Preceptor Guide. Current version. Published by the Pharmacy Board of Australia. Available on the Pharmacy Board of Australia website at Pharmacy Board of Australia - Home.

2. Performance Outcomes Framework 2020. Published by the Published by the Australian Pharmacy Council (APC). Available on the APC website at Home | Australian Pharmacy Council

3. Intern Year Assessment Blueprint. Current version. Published by the Australian Pharmacy Council (APC). Available on the APC website at Home | Australian Pharmacy Council

[1] Accreditation Standards for Pharmacy Programs in Australia. Performance Outcomes Framework 2020. ©Australian Pharmacy Council at Accreditation Standards for Pharmacy Programs | Australian Pharmacy Council.

[2] Accreditation Standards for Pharmacy Programs in Australia 2020. ©Australian Pharmacy Council at Accreditation Standards for Pharmacy Programs | Australian Pharmacy Council.

Overview: Entrustable professional activity (EPA) 2: Compounding pharmaceutical products

This EPA should be understood and undertaken within the overarching principles of Quality Use of Medicines (QUM) and person-centred care.

In the context of this EPA, compounding pharmaceutical products includes both the cognitive and technical aspects of the process. Cognitive aspects include reasoning and decision-making regarding the appropriateness of making a compounded product, taking into account the relative risks and benefits, patient-specific details, co-morbidities, adverse and allergic reactions, drug interactions and contraindications, and other aspects which affect the safety and/or efficacy of a compounded product. Technical aspects include accuracy and attention to detail in making calculations and carrying out the physical manipulations so that the patient receives the correct medication, and all legal requirements are met.

This EPA has been designed to align with the current Pharmacy Board of Australia (PharmBA) requirements for the preparation of extemporaneously compounded preparations by interns during the period of supervised practice. It has been noted that interns working within hospital pharmacy are often required to undertake batch manufacturing, and this aspect is not fully aligned with PharmBA requirements.

For the purposes of this EPA, the definitive reference source is the compounding section of the current version of the *Australian Pharmaceutical Formulary and Handbook* (APF).

EPA Description

EPA Title	Compounding pharmaceutical products
Specifications and limitations	**Outcome**: Compounded pharmaceutical products are appropriately, safely, and accurately prepared and supplied to the correct patient, using an appropriate container and with accurate and comprehensive labelling; supply reflects the intentions of the prescriber and is consistent with PharmBA and Therapeutic Goods Administration (TGA) guidelines. **Specifications**: Need for a compounded preparation is established (i.e., no suitable proprietary product available). Prescription or request is checked for legality, validity, and completeness according to all relevant jurisdictional requirements. Suitable formulation is identified. Availability of required materials is confirmed (ingredients, equipment, containers).

	Suitable area for compounding is identified and prepared appropriately, including use of Personal Protective Equipment (PPE). Accurate calculations are performed and recorded. Appropriate preparation method is determined and recorded. Appropriate preparation techniques are used. Appropriate container is selected and used. All required labels are attached appropriately to the product, including expiry date and storage conditions. Final product is checked for quality and completeness. Checks are carried out at appropriate stages of the process. Products and paperwork are stored appropriately prior to collection. Patient receives correct product and associated paperwork. **Limitations**: Does not include complex compounding[3] as defined by the PharmBA publication *Guidelines on compounding of medicines.*
Potential risks in case of failure	Inappropriate and/or inaccurate preparation of compounded products may lead to individual patient harm and/or harm to the health and safety of the public.
Most relevant performance outcomes	**3.15:** preparing and supplying extemporaneously compounded medications safely and accurately in accordance with current legislation, scope of practice, PharmBA Guidelines, and other relevant jurisdictional requirements. **4.2:** identifying and acknowledging professional limitations and seeking appropriate support where necessary, including additional professional education and/or referral of patients to other health care professionals. **5.3:** recognising and responding to the inherent complexity, ambiguity, and uncertainty of contemporary and future professional practice.

[3] Interns are not precluded from carrying out complex compounding under appropriate supervision; however, this EPA does not lead to entrustment for this type of compounding.

Required knowledge, skills, attitudes, and experiences (A RICH)	Knowledge of PharmBA and TGA guidelines (C) Knowledge of formulation science and contamination control (C) Calculation skills (C) Skills in physical techniques (C) Attention to detail (R) Person-centred approach (I) Awareness of personal limitations (H) Willingness to seek assistance (H)
Information sources to assess progress and ground a summative entrustment decision	Documentation required by the PharmBA Short practice observations (SPO) – template provided Reflection on performance by intern – written or oral[4] Entrustment discussions – guidance and template provided
Entrustment/supervision level expected at which stage of training	Level 2 or 3 on entry to intern year Level 4 by end of intern year; may be entrusted earlier
Time period to expiration if not practiced	Not applicable to intern year.

[4] A template provided as part of the In Training Assessment (ITA) reflection activity is a useful resource.

Information sources

Documentation required by the Pharmacy Board of Australia

As set out in the Intern pharmacist and preceptor guide[5], the PharmBA requires evidence that interns are assessed on their ability to prepare (compound) extemporaneous products in the supervised practice site as part of the Intern Training Program (ITP). This assessment requires each intern to prepare 6 different products, with the specific details set out in a "letter to preceptors". Evidence for completion of this assessment comprises a written report form for each product, and a statutory declaration by the preceptor. These documents are returned to the ITP provider.

Documentation required - Australian Pharmaceutical Formulary (APF) and Handbook

No specific guidance is provided in the PharmBA documentation about the requirements for the compounding form to be used as a record for each product, of the details of risk assessments carried out, calculations and preparation method used, ingredient batch numbers and expiry dates, and container chosen. However, the APF includes an example of such a form which facilitates recording of all necessary details.

It is expected that a form such as that described in the APF is used as a formal record of the preparation of any compounded product, including those which are prepared by interns for the purposes of this EPA. The example published in the current version of the APF is recommended for use either as it is, or as the basis for a form tailored to the needs of a particular workplace.

It is noted that the nature of compounding, and the associated records generated, in hospital pharmacies often differs from that in community pharmacies, with the former involving a greater use of batch preparation forms for preparation of commonly used products.

Short practice observations (SPOs)

When included as part of an intern's overall Training and Development Plan for the intern year, further evidence to support entrustment decisions may be necessary, and could include observation of interns' preparation of products in addition to those required by the PharmBA. This is particularly important since the PharmBA requirements exclude the preparation of more than one product from a particular category.

A short practice observation (SPO) would generally involve a supervisor observing the intern while preparing a compounded product, from completing all preliminary documentation for the compounded product, including calculations, through to the appraisal of the final labelled product.

[5] Refer to the Pharmacy Board website for the most current version.

In addition to the 6 products mandated by the PharmBA, additional SPOs may be considered appropriate for assessing the performance of the intern on this EPA. In the context of hospital pharmacy practice, preparation of batches could be included in these additional SPOs. In the context of community pharmacy, repeat preparation of simple products (e.g., addition of simple ingredients to pre-prepared creams, preparation of simple mixtures) is also recommended where improvements are considered necessary.

Ideally, SPOs should be spaced throughout the period of supervised practice to allow for observation of improvements in performance. It is not intended that SPOs be carried out in clusters or close together in time, but regularly spaced and scheduled at times when an intern is considered to have improved since a previous SPO. At the end of each SPO and on completion of the 6 mandatory products, an entrustment discussion (see below) should occur between the intern and the observers.

There are two forms associated with feedback and assessment of intern performance on this EPA. These are the:

1. Short Practice Observation Feedback Form - EPA 2 - Compounding
2. Assessment of EPA 2 - Compounding

Both forms should be completed after each SPO.

Following the SPO, the intern should complete the sections on the Feedback form which ask for their reflection on their own performance. Once the intern has completed these sections, a discussion should be held with the supervisor who should provide their feedback. Following this, an entrustment discussion (see below) should be held between intern and supervisor, with documentation carried out using Assessment form. Following the entrustment discussion, the intern should spend some time reflecting on all feedback, and create a Development Plan to address any areas where improvements could be made. This Development Plan can be used as the basis for selecting the next opportunity for an SPO, and also as the basis for evaluating progress during the intern year.

Calculations

Given the critical nature of correct calculations, formal assessment of the intern's capacity to make consistently accurate arithmetic manipulations may also be considered as part of the evidence associated with entrustment.

Flowchart

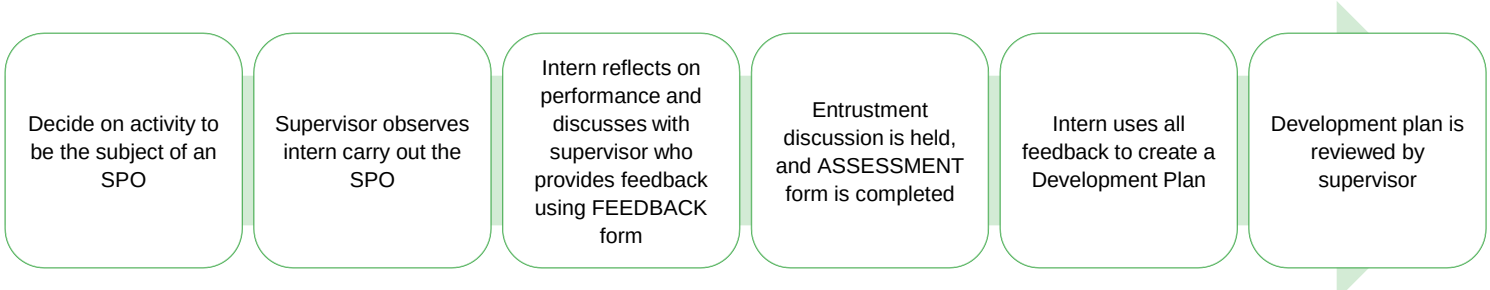

Figure 1: Steps in assessment of EPA 2 – Compounding

Entrustment discussions

The entrustment discussion is intended to provide additional evidence to support (or not) a decision that an intern can be trusted to perform the EPA with decreasing supervision (more autonomy).

The preceptor should require the intern to:

1. explain the activity
2. demonstrate depth of knowledge
3. demonstrate awareness of risks
4. demonstrate adaptive capacity and expertise (by answering “what-if” questions).

Key elements of entrustment discussion

- Discussion of intern’s reflection on performance
- Review of PharmBA paperwork
- Review of SPO reports
- Use of probing questions such as:
    - appropriate sources of formulas
    - appropriate sources of advice and information
- Evaluation of intern’s understanding of risks:
    - risks vs benefits of using a compounded rather than proprietary product
    - harm associated with calculation errors, process failures and poor labelling
    - key check points in the process
    - intern’s possible “blind spots”
- Use of “what-if” questions such as:
    - unable to locate appropriate formulation
    - unable to contact prescriber for clarification
    - pressure from patient
    - unable to source all ingredients and equipment
    - new product which intern has never prepared

Ad hoc entrustment discussions can be held at any stage of the intern year and should form part of the overall evidence on which a summative entrustment decision is based. An ad hoc entrustment decision should form part of any formal SPO, and the outcomes recorded (a template is provided). The aim should be to give the intern a clear idea of where performance has been strong and where further improvement is necessary.

When either the intern or preceptor considers that the intern may be ready for assessment, a **summative entrustment discussion** may be held. At this discussion, evidence from previous activities, feedback and discussions should be reviewed, and the preceptor should ask additional questions until such time as a decision in favour of entrustment to perform the activity with greater autonomy (decreasing supervision) can be justified.

For level 4 entrustment, following a summative entrustment discussion, and based on available evidence, the preceptor will need to answer the questions:

> **Do I trust this intern to compound simple pharmaceutical products as safely and accurately as a fully registered pharmacist?**
>
> **Do I trust this intern to compound simple pharmaceutical products which have not been encountered previously?**

If the answers to both questions are **YES**, a level 4 entrustment decision may be appropriate. It is critical to note, however, that even when an intern has been deemed entrustable at level 4, the Pharmacy Board requirements for supervision while the intern is provisionally registered still apply. In addition, at least one pharmacist with general registration must be physically present on the premises in accordance with legal requirements under the Health Practitioner Regulation National Law.

From a practical perspective, within the individual workplace, supervisors may identify that an intern is entrustable at level 4 but should still ensure that their work is adequately checked. This may entail allowing the intern to carry out the activity independently but putting measures in place to require verification of accuracy and appropriateness. As an example, an intern may carry out the EPA with little supervision, but a final check is carried out by a generally registered pharmacist before supplying to the patient. Supervisors will need to balance the level of supervision that is required by the intern with the professional responsibility of the supervisor to ensure accountability and patient safety.

As part of the final submission by preceptors to ITP providers at the end of the supervised practice period, ITP providers should consider including a declaration by the preceptor as to the level of entrustment given to the intern for this EPA at the time of the final declaration.

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council

Australian Pharmacy Council
Level 1, 15 Lancaster Place
Majura Park, Canberra Airport, ACT 2609, Ngunnawal Country
p +61 2 6188 4288 | www.pharmacycouncil.org.au