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| Entrustable Professional Activity (EPA) 2: Compounding medicinesPreceptor and Intern User Guide |
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# List of Abbreviations

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| Abbreviation | Term |
| APC | Australian Pharmacy Council |
| APF | Australian Pharmaceutical Formulary and Handbook |
| A RICH | Agency, Reliability, Integrity, Capability, Humility |
| EPA | Entrustable Professional Activity |
| ITA act | 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 medicines developed by the Australian Pharmacy Council (APC) to assist with the assessment of an intern’s achievement of one or more of the performance outcomes required to be demonstrated at the point of general registration as a pharmacist.

**Interns** will use the associated forms and the templates for reflection and for seeking feedback on their performance from their supervisor, on compounding pharmaceutical products.

**Preceptors and supervising pharmacists** (collectively referred to as Supervisors) will use the associated forms and templates to document observations of intern performance, provide feedback, assess intern performance and jointly formulate the intern’s development plan.

**Intern Training Program providers** will incorporate this EPA 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.

# Supporting 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 [www.pharmacyboard.gov.au](http://www.pharmacyboard.gov.au).
2. Performance Outcomes Framework 2020. Published by the Australian Pharmacy Council (APC). Available on the APC website at [www.pharmacycouncil.org.au](http://www.pharmacycouncil.org.au).
3. Intern Year Assessment Blueprint. Current version. Published by the Australian Pharmacy Council (APC). Available on the APC website at [www.pharmacycouncil.org.au](http://www.pharmacycouncil.org.au).

# Overview: Entrustable Professional Activity (EPA) 2: Compounding medicines

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 medicines 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 medicines |
| **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, the APF 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[[1]](#footnote-2) 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. |
| **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 providedReflection on performance by intern – written or oral[[2]](#footnote-3)Entrustment discussions – guidance and template provided |
| **Entrustment/supervision level expected at which stage of training** | Level 2 or 3 on entry to intern yearLevel 4 by end of intern year; may be entrusted earlier |
| **Time period to expiration if not practiced** | Not applicable to intern year. |

# Information sources

## Documentation required by the Pharmacy Board of Australia

As set out in the Intern pharmacist and preceptor guide[[3]](#footnote-4), 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.

## Record of compounded medicines

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.

## 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 a short practice observation (SPO).

## 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.

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. After the SPO, an entrustment discussion (see below) should occur between the intern and the observer(s).

Following the entrustment discussion and entrustment decision (see below), the intern creates 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 as the basis for evaluating progress during the intern year.

All aspects for observation by the supervisor on this form should be addressed for initial compounding SPOs, however as interns gain more experience and expertise, the focus should be on changes since the last SPO, and all aspects may not need to be answered in detail.

# Entrustment discussions

The entrustment discussion encompasses more than simply feedback about the intern’s performance of the EPA. The supervisor also seeks to understand the intern’s ability to perform in future scenarios when the context, patient and parameters may be different to what has been observed. It is not feasible to observe every possible scenario and context during the supervised practice period.

An entrustment discussion does not have to occur immediately after the SPO but should be scheduled within a reasonable time period to maximise opportunity for learning and development. These discussions provide additional evidence to support (or not) a decision that an intern can be entrusted to perform the EPA with increased autonomy, thereby requiring less supervision. Using the four-step framework, 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 discussions

* 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

Supervisor feedback following these discussions should be recorded in the *Assessment of EPA- 2 Compounding medicines form*. Feedback should be simple and concise and can be documented using the KEEP, START, STOP approach to feedback. This is a useful framework for receiving and delivering feedback in three sections. Supervisors may find it beneficial to approach feedback by responding to the following three questions.

1. What should the Intern KEEP doing?
2. What should the intern START doing?
3. What should the intern STOP doing?

# Entrustment Decisions

Entrustment decisions are NOT a rating of the intern’s performance. Entrustment involves making a holistic decision about the level of supervision the intern will need to continue to practice based on triangulation of all the information gathered about the intern’s capability to safely and effectively compound pharmaceutical products. This information is based on the supervisor’s professional judgement on the SPO(s), review of any compounding logs, intern reflection, the feedback discussions, and the quality of the compounded product. Simply put, an entrustment decision answers the question “What level of supervision will this intern require going forward, based on what I have gathered about their performance and abilities?”

## Ad hoc entrustment decisions

An ad hoc entrustment decision can form part of any SPO. The aim of an ad hoc entrustment decision should be to provide the intern with a clear understanding of where performance has been strong and areas where further improvement is necessary. Ad hoc entrustment decisions should form part of the overall evidence on which a summative entrustment decision is based.

## Summative entrustment decisions

**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. 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.

# Summary

Figure : Steps in assessment of EPA

1. Interns are not precluded from carrying out complex compounding under appropriate supervision; however, this EPA does not lead to entrustment for complex compounding. [↑](#footnote-ref-2)
2. A template provided as part of the In Training Assessment (ITA) reflection activity is a useful resource. [↑](#footnote-ref-3)
3. Refer to the Pharmacy Board website for the most current version. [↑](#footnote-ref-4)