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| Entrustable Professional Activity (EPA) 2:   Compounding pharmaceutical products |
| April 2021 | Version 0.3 |

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Entrustable Professional Activity (EPA) 2:   
Compounding pharmaceutical products

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| **Overview** | Compounding pharmaceutical products includes both the cognitive and technical aspects of the process. Cognitive aspects include reasoning and decision-making in regard to 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. |
| **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 Pharmacy Board of Australia (PharmBA), and Therapeutic Goods Administration (TGA) guidelines and the Australian Pharmaceutical Formulary and Handbook (APF).  **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 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 as defined by the PharmBA publication [Guidelines on compounding of medicines](https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD15%2f16205&dbid=AP&chksum=3QlnioMt0DhI0PsjaoB83A%3d%3d)\*. |
| **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 and the APF (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) – report template provided  Reflection on performance by intern – written or oral#  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 practised** | Not applicable to intern year. |

\*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.

# The template provided as part of the ITA Activity – Reflection is a useful resource for this reflection by the intern.

# Information sources

## Documentation required by the Pharmacy Board of Australia (PharmBA)

As set out in the [Intern pharmacist and preceptor guide](https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2f4166%5Bv5%5D&dbid=AP&chksum=tYDwKFzipNvv3aqgsm7NsQ%3d%3d), 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](https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2f4169&dbid=AP&chksum=CVJ3Gf77Y5ApqGUeAko%2bxQ%3d%3d). Evidence for completion of this assessment comprises a [written report form](https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2f4171&dbid=AP&chksum=XwlIENJzx6j2gSoCJkX6Ww%3d%3d) for each product, and a [statutory declaration](https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2f4172&dbid=AP&chksum=A0t%2fGbpJPyMOPpZQm73f%2fg%3d%3d) by the preceptor. These documents are returned to the ITP provider.

## Short practice observations (SPOs)

Further evidence to support a level 4 entrustment decision would 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 supervising pharmacist observing the intern while preparing a compounded product, from completing all 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, a minimum of 6 further SPOs is considered appropriate for assessing the performance of the intern on this EPA. In the context of hospital pharmacy practice, preparation of batches is encompassed by these additional SPOs. 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.

## 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 a lower level of supervision (i.e. to progress from one level of supervision to the next). 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

* 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 for guidance). 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 level 4 supervision, a **summative entrustment discussion** may be held. At this discussion, evidence from previous activities, feedback and discussions should be reviewed, and the supervisor should ask additional questions until such time as a decision in favour of entrustment can be justified.

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 important to note, however, that even when an intern has been entrusted at level 4, the Pharmacy Board requirements for supervision while the intern is provisionally registered still apply (See EPA Guide).

Template for Short practice observation

Compounding pharmaceutical products

Intern name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_ Assessor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Product name or formula: \_\_\_\_\_\_\_\_\_­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Aspect** | **Assessed (circle one)** | | **Comments** |
| **Appropriate formulation chosen** | **✓** | **X** |  |
| **Calculations correct and recorded** | **✓** | **X** |  |
| **Method recorded appropriately** | **✓** | **X** |  |
| **Compounding area appropriately prepared** | **✓** | **X** |  |
| **Correct ingredients and equipment chosen** | **✓** | **X** |  |
| **Ingredient expiry dates checked** | **✓** | **X** |  |
| **Appropriate preparation process followed** | **✓** | **X** |  |
| **Accurate transfer to appropriate container** | **✓** | **X** |  |
| **Labelling completed accurately and fully** | **✓** | **X** |  |
| **Final product of required quality** | **✓** | **X** |  |

Template for entrustment discussion

Compounding pharmaceutical products

Intern name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_ Assessor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ad hoc entrustment discussion  Summative entrustment discussion

(Tick appropriate box)

|  |  |
| --- | --- |
| **Discussion component** | **Assessor’s comments** |
| **Reflection on performance – areas of strength and areas for improvement** |  |
| **Ability to access information when needed** |  |
| **Risk awareness** |  |
| **What-if questions …** |  |
| **Other comments** |  |
| **Entrustment decision** | Intern entrusted at level  1  2  3  4 |

Assessment of EPA:

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| Level 1 | Observe only, even with direct supervision |
| Level 2 | Perform with direct, proactive supervision and intervention |
| Level 3 | Perform with indirect proximal (nearby) supervision, on request and quickly available |
| Level 4 | Perform with minimal supervision, available if needed, essentially independent performance\* |

\*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.