

Compounding: From Basics to Modern Technology

Tammy Nguyen B. Pharm, MPS, Compounding Pharmacist, Medisca Australia

&

Patricia Ullmann B.Pharm, Training and Technical Services Manager, Medisca Australia

AFTER COMPLETING THIS ACTIVITY, PHARMACISTS SHOULD BE ABLE TO:

1. Describe the equipment and technologies used in compounding
2. Describe the processes of trituration and homogenisation
3. List variables used to calculate the minimum accurately weighable quantity (MACQ) of electronic balances

The 2016 Standards addressed by this activity include: 1.1, 1.2, 1.3, 3.2, 3.4

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Introduction

The preparation of extemporaneous compounds is a process composed of multiple procedures. Each procedure in the process assures the quality of the final preparation. This article discusses the rationales behind the procedures, the equipment, and the technologies used during the compounding process today.

The flowchart depicted in figure 1 is a summary of the core steps specific to the preparation of compounded medication.

A systemic approach to quality assurance requires the design and implementation of appropriate standardised procedures. Quality assurance requires verification through both qualitative and quantitative quality control measures. In Australia, quality assurance is one of the criteria outlined in the *Professional Practice Standards* for pharmacists, standard 5.²

The entire Standard is based on the patient-centred care model, as shown in figure 2.

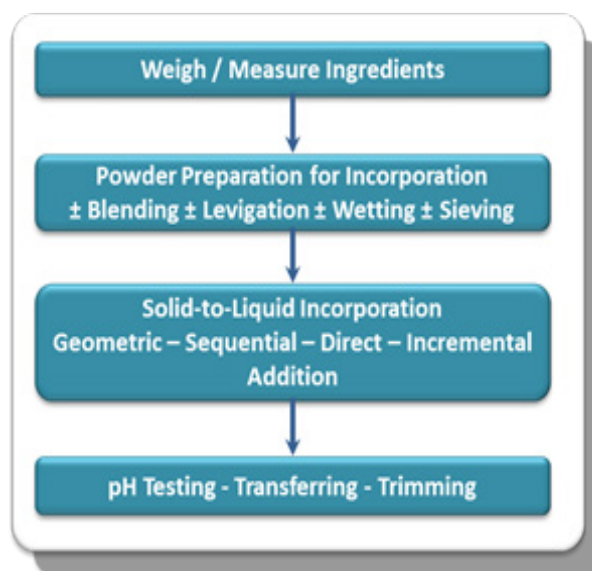


Figure 1: Steps involved in the preparation of compounds¹



Figure 2: Criteria to achieve the Compounding Standard.²

Weigh and Measure Ingredients

As technology has improved in all walks of life, the same can be said for the modern compounding pharmacy. Gone are the days of the vintage torsion balance scales that were commonplace in the pharmacy dispensary. The rise of the electronic balance, due to its higher accuracy compared to its counterpart, has led to its inclusion as a compulsory piece of equipment by several state and territory pharmacy boards and authorities.^{3,4} The inclusion is immaterial to whether the pharmacy is conducting compounding on the premises.

This higher accuracy does not render this modern piece of equipment infallible. Electronic balances, like all balances, have their limitations. Of particular interest to compounding pharmacists, is the lowest weight that may be measured accurately.

The lowest weighable amounts may be referred to as minimum accurately weighable quantity (MAWQ). MAWQ is the smallest weight or mass that will produce

no greater than a predetermined fraction of error.^{5,6} MAWQ calculations rely on two main variables: sensitivity requirement and maximum permissible error permitted during weighing.^{5,6}

Sensitivity requirement is also known as linearity when referring to top pan electronic digital display balances.⁷ The *United States Pharmacopoeia* (USP) defines linearity as the ability of a balance to follow the linear relationship between load and the indicating weight values.⁸ This value is often stated by the manufacturer in the user manual of the instrument.

Linearity should not be confused with readability, which refers to the scale unit of the equipment. E.g. a 3-digit balance has a readability of 0.001g.

Maximum permissible error, also known as tolerance, is the upper limit of acceptable

departure from the actual value. This is a fixed amount, but varies depending on the reference or the type of chemical being handled. The *Australian Pharmaceutical Formulary 23rd Edition* restricts the maximum permissible error to $\pm 2\%$.⁹

Assuming a balance with three decimal places, with a readability of 0.001, has a linearity of 0.001, the MAWQ can be calculated as such:

$$MAWQ = \frac{1 \text{ mg}}{2} \times 100\% = 50 \text{ mg or } 0.050 \text{ g}$$

The most current edition of the *Australian Pharmaceutical Formulary (Ed 24)* no longer includes this definition, and at the time of this publication, it has not been updated.¹⁰

The *United States Pharmacopoeia* chapters <41> and <1251> outlines the requirement for balances used to measure any material that needs to be accurately weighed.^{8,11} This is significant because when a USP monograph requires a material to be accurately weighed, the equipment used must conform to the specifications in these chapters.⁸

The *Professional Practice Standards* requires equipment, including instruments used in weighing, to be maintained and checked at regular intervals.² External third party providers accredited by the National Association of Testing Authorities (NATA) may certify balances are operating within parameters.¹²

$$MAWQ = \frac{\text{Sensitivity Requirements (linearity)}}{\% \text{ Error (Tolerance)}} \times 100\%$$

Figure 3. Minimum accurately weighable quantity (MAWQ) formula

Once the limitation of the electronic balance is known, it should be displayed or communicated to staff through an appropriate Standard Operating Procedure (SOP).² Prior to each day's operation of the balance, the instrument should be appropriately levelled and calibrated.² This procedure, as well as any other routine maintenance, should be outlined, implemented and documented through SOPs and logs.²

SOPs often instruct that measurements on a balance need be performed in the powder containment hood, in order to prevent undue exposure of chemicals to the operator. Operating inside a powder containment hood can be challenging as there is a constant flow of air towards the High Efficiency Particulate Air (HEPA) filter.

A HEPA filter is the air filtration unit found in primary engineering controls such as powder containment hoods and biological safety cabinets.¹³ The filtration units can be preceded by a pre-filter, which initially removes larger particulates in the air before the air flows through the HEPA filter.¹³ HEPA filters are also extensively used in secondary engineering controls for heating, ventilation and air conditioning (HVAC) systems.¹³ Air filtration is an effective mechanism of reducing the risk of chemical exposure to the operator. The appropriate primary and secondary engineering controls need to be selected, built and commissioned with consideration to the chemicals handled; and the associated risks to the operators, patients, caregivers and the environment.²

Most electronic balances are supplied with a draft shield or breeze break. As the name suggests, this additional accessory is used to reduce airflow or turbulence directly on the measurement area of the balance. Excessive airflow directly on the weighing pan destabilises the balance, resulting in inaccurate readings.¹⁴ While electronic balances are most often associated with the weighing of powders, this instrument can also be used to weigh liquids.

It is important for the pharmacists to identify what type of graduated measuring device is being used in the laboratory⁵ and to understand the purpose of each type. Measuring liquids using a graduated cylinder or volumetric flask, relies on the performance of an eye level reading of the meniscus. Graduated glassware can be calibrated "to deliver" (TD) certain volumes while others are calibrated "to contain" (TC) specific volumes. Manufacturers of glassware specify the temperature and pressure at which the calibrations were performed.

Reading of a meniscus can be challenging as the shape of the meniscus changes with the type of liquid being measured. Liquids with high surface tensions will appear to have concave up (or simply "concave") meniscus, whereas low surface tension liquids will have a concave down meniscus¹ (also known as "convex"). See figure 4.

Another way to measure liquids would be to weigh the mass of the volume, based on the density of the liquid. Both liquids and solids can be expressed as density unit gm/mL (also

expressed as cubic centimetres in some references). Liquids can be converted from a volumetric measure to a weight. This can be beneficial as it:

- eliminates any potential errors that can arise from reading a meniscus
- reduces the steps (and associated loss) in the transfer of liquids across multiple receptacles

For example, rather than measuring in a graduated cylinder and transferring into a beaker, the liquid may be weighed directly into the breaker.¹

$$\text{Density} = \frac{\text{Mass}}{\text{Volume}}$$

Geometric Addition or Dilution

When two or more components are mixed, the standard procedure used to achieve a homogenous blend is geometric addition.¹⁵ Geometric addition is synonymous with the terms "geometric dilution" and "method of doubling". Prior to this step, the pharmacist or compounding technician may triturate or sieve the powders to ensure they are of the same particle size, as homogenous powder blends are difficult to achieve if the powders incorporated are of differing particle size.¹⁵

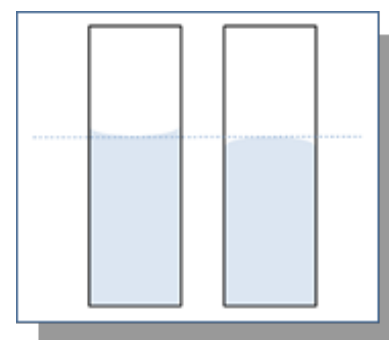


Figure 4: Curvature of the meniscus¹

Trituration or milling is the act of reducing the particle size of a powder.¹⁵ This may be achieved by one of two different procedures, depending on the final dosage form. Triturating may be achieved by the continuous grinding or rubbing of the powder in a mortar with a pestle.¹⁷ Alternatively, trituration may be achieved by levigation or wetting. This involves the addition of liquid to the powder, to disperse the active within the liquid.¹⁸ Trituration or milling can also be achieved mechanically through the use of equipment.

Trituration is also a crucial step in the preparation of topical dosage forms intended for transdermal application.¹⁶ The particle size of the active pharmaceutical ingredient (API) is of one of the considerations when transdermal delivery systems are developed.

The term trituration also has a different meaning in pharmacy practice. Apart from the above meaning, trituration can refer to the dilution of an API with a suitable powdered diluent in a definite weight proportion.¹⁷ The diluted mixture is referred to as a triturate or aliquot.

Geometric addition is a technique used to achieve homogeneity. Homogeneity is imperative to ensure active ingredients are evenly dispersed within a preparation resulting in individual dosage units of equal strength, such as in the preparation of powder blends for encapsulation. For more information on encapsulation, refer to Rebecca O'Grady and Patricia Ullman's Australian Journal of Pharmacy article, "*Compounding: what was it... when, why and what is it today?*" which is available on the

AJP website at www.AJP.com.au/cpd-activities

Geometric addition refers to the procedure of blending small quantities of powder,¹⁵ where an API, is added to larger quantities of powder, usually diluents or excipients. The compounding pharmacist or technician starts with ingredients of the smallest quantity and adds the second least ingredient incrementally by doubling the portions being mixed.¹ This approximation should be done by weight, not by volume. The procedure is repeated until all ingredients are incorporated.

Traditionally pharmacists perform this technique with powders using a mortar and pestle.¹⁵ Mortars and pestles are commonly available in the following materials: glass, ceramic and porcelain. The ceramic and porcelain materials are porous but are more effective in trituration compared to glass.¹⁵ The smooth surface of the glass results in less loss of ingredients, hence glass is preferred when only geometric dilution is required.

Technologies such as V-mixers, oloid tumblers, and planetary-motion mixers, are now available to compounding pharmacists to achieve these procedures more efficiently. Such technologies are designed to provide an even distribution of actives within preparations without the need for geometric addition. They are contained systems which can reduce the exposure of hazardous chemicals to compounding pharmacists and technicians. One example, is the Inversina which is an oloid tumbler mixer. The technology produces

homogeneity for powders or liquids by rotating a mixing vessel along an oloid geometric pathway.¹⁹ The oloid pathway is a 3- dimensional figure 8 shape, and allows constant inversion upon each rotation.¹⁹ This technology can homogenise both powders and liquids. In the manual model, the handle is rotated by hand at approximately 60 RPMs to achieve a continuous mixing motion. In both the manual and the motorised models, powders require trituration before homogenisation, as the Inversina (like most mixing technologies) does not reduce particle size. Powders incorporated into liquids using an Inversina require levigation prior to the addition of a liquid diluent.¹⁹

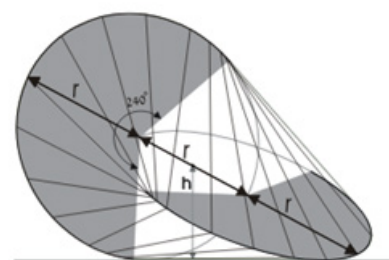


Figure 5: Geometric Oloid¹⁸



Figure 6: Manual tumbler mixer, Inversina¹⁸

Another technology used for homogenisation is an Electronic Mortar and Pestle (EMP). The two major brands available in Australia are the Unguator[®] and Samix[®]. Their latest models have validated mixing programs based on concentration, volume

and the type of the preparation compounded; while their earlier models require the operator to determine and input the speed and mixing time into the EMP computer manually.^{20,21} Details of the settings need to be documented as part of the Master Formulation Record to ensure standardisation and hence repeatability of the formulation. Master formulation records are referred to as master extemporaneous records in the APF.²

EMPs are designed to prepare homogeneous semi-solid dosage forms such as creams, ointments and pastes. An EMP differs from the previous technology, as it allows for the homogenous dispersion of solids into liquids in a single-step procedure.^{20,21} An EMP can also be used in the preparation of gels and suspensions.^{20,21} Some EMP models can homogenise powders but require the addition of an inert lubricant such as aerosil, as well as the use of a non-standard disposable mixing blade.²²

The device homogenises preparations by using both horizontal and vertical mixing movements via mixing blades contained in a polypropylene jar. The mixing blade rotates at speeds between 200-2500 rpm depending on the machine and engine size.^{20,21} There is a shear force between the blade and side of the EMP jar which results in some particle size reduction^{20,21}, although powders that are crystalline and granular may still need to be triturated before incorporation.

The high-speed rotation of the EMP can result in the aeration of the final preparation. For

example, during the preparation of a cream, the air inside the EMP jar will be incorporated into the emulsion. This results in pockets of air being dispersed through the semi-solid compound. The excess air, increases the final volume of preparation which can have consequences for patients using a volumetric metered dose device. Inaccurate dosing will result if an aerated preparation is dispensed. A deaeration step may need to be performed prior to dispensing.

Verification of the final preparation is essential in ensuring quality control and patient safety. Verification is a quality control step to ensure the preparation conforms to expected specifications and has been prepared in accordance with the Master Formulation Record.^{23,24} Verification procedures can be both qualitative or quantitative.²³

An example of qualitative verification is a visual and physical check of an emulsion. The consistency, continuity and colour of an emulsion is a visual indication the compound is homogenous.²⁴ Physical verification may involve checking the appearance and grittiness of the emulsion. Excessively gritty emulsions can be indicative that further trituration is required. Grittiness is not just a consideration of unsightliness in a preparation, as this physical

property can impact the expected performance of a compound.²⁴ For example, a topical local anaesthetic needs to penetrate through the epidermal and dermal layers of the skin in order to numb the area. This is not possible if the particles of the API are too large to penetrate through the stratum corneum.²⁵

An instrument that can be used for both deaeration and trituration or milling of semi-solids and liquids, is an ointment mill.^{26,27} Despite its name, this technology is not solely used with ointments. It can also be used to mill and deaerate a range of dosage forms including^{26,27}:

- emulsions
- gels
- suspensions
- pastes

The preparation is “run” through the mill where there are generally three rollers, made either from a ceramic or aluminium oxide material.^{27,28} The preparation is fed through the instrument on the roller furthest from the operator. The preparation passes through the two gaps formed between the three rollers.^{27,28} The shearing action of the rollers results in the reduction of particle size and dispersion of powders.²⁸ This technology cannot be used for homogenisation. The range of function can vary between models and brands.



Figure 7: Ointment Mill²⁷



Figure 8: Planetary mixer Mazerustar^{®29}

An example of a planetary-motion mixer is the Mazerustar[®], shown in figure 8. Similar to the EMP, it can be used to prepare semi-solid dosage formulations. This technology uses a planetary mixing action to homogenise both solids, liquids and semi-solids.²⁹ The mixing vessel is balanced with a counterweight and the instrument rotates on 2 axes at up to 2000RPM.²⁹

This technology has the capability of milling or triturating powders in a step conducted prior to mixing, before powder is homogenised with other ingredients.²⁹

The technology also has a vacuum-like feature which removes air entrapment within the mixing vessel, which reduces aeration of the final preparation.²⁹

These technologies allow pharmacists to minimise any potential loss occurring during the compounding procedure, as the processes are performed in a single contained system. This has implications on not only the accuracy and quality for the

final preparation, but also by favourably impacting the:

- risks to the operator
- risks of cross-contamination which may affect patients, caregivers, and the environment
- the monetary cost to the business from materials lost during the compounding process.

Homogeneity and Content Uniformity

As discussed, homogeneity of ingredients within a preparation is part of the quality assurance for content uniformity. Uniformity of content should not be confused with uniformity of dosage units. It is possible for preparations to have uniformity of dosage units but not have content uniformity. Both these terms are defined in the United States Pharmacopoeia (USP), which has been harmonised with both the European and Japanese Pharmacopoeias.³⁰ The USP outlines physical tests to assess both these characteristics in finished preparations.³⁰ These are quantitative assessments.

Uniformity of dosage units can be

assessed using a weight-variation assessment.³⁰ This assessment is only applicable to some dosage forms, including but not limited to, capsules and tablets. Weight variation assessments can be performed in the pharmacy. The following procedure describes an example of a weight variation test for 100 dosage units:¹⁵

1. Calibrate and tare balance to be used
2. Select five dosage units and weigh them individually
3. Record the individual weights
4. Determine weight variation

The test sample can either be 10 dosage units or 5% of the total formulation yield, whichever sample is less.²⁴

Uniformity of content involves the assaying of a representative proportion of the finished product.²⁴ This test involves additional laboratory equipment and access to appropriate analytical chemical standards to which compounding pharmacists may not have easy accessibility. Often this procedure needs to be outsourced to an analytical laboratory.

Routine analytical testing on finished preparations is referred to in the *Professional Practice Standards* for pharmacists.² Pharmacists do not need to respond only reactively, after a reported incident or failure following a quality control procedure. Proactive, routine and random testing of compounded medications may be used to identify potential issues with procedures, techniques, and staff training - and even technologies themselves.

Specific State and Territory boards may stipulate such

testing as a requirement for pharmacies undertaking complex compounding. In South Australia, the Pharmacy Regulatory Authority SA (PRASA) requires pharmacies to carry out testing of prepared products according to a documented process.⁴ The testing should be done at random, and at specified intervals. The Victorian Pharmacy Authority (VPA) Guidelines, also mandates finished product testing as a requirement.³¹

Best practice involves finished product testing of every dosage form prepared by the compounding pharmacy. This procedure can also be used to determine the competency of individual personnel preparing compounded medicines.

Finished product testing assesses personnel involved in compounding to ensure they have been appropriately trained for the dosage forms they prepare. In addition to routine testing, there are specific types of formulations where testing may be beneficial. For high-risk compounding, such as preparations including APIs with a low therapeutic index, finished product testing can be used as a means of verifying a formulation, and its preparation procedure. Verification through finished product testing ensures a high-risk compound will perform as expected and is crucial for optimal patient care.

Conclusion

The basic concepts for the preparation of extemporaneous compounds have not changed significantly over the last few years. However, the technologies available to pharmacists have significantly increased over time.

Although compounding staff

can be manual-dexterity skill trained, technologies may reliably eliminate operator-dependent variables such as the strength, size and experience of the compounder. The main benefit of the modern technologies which streamline procedures is the standardisation of compounded preparations to be repeatable and consistent. Selection, installation, commissioning, use, maintenance and documentation of appropriate technologies, when incorporated into SOPs, result in increased efficacy, reliability and validity of compounded preparations, thereby supporting improved patient outcomes.² Reduction in labour and improved occupational health and safety of operators are also benefits.

The pharmacist is ultimately responsible for the quality of the dispensed compounded preparation.² Best practice procedures incorporate a verification step to ensure the compound has been prepared according to the Master Formulation Record and meets required specifications.¹⁰

Quality is enshrined in law, irrespective of whether the medication has been prepared extemporaneously or bulk manufactured.³² From the initial step of weighing ingredients through to final verification of the finished preparation, the compounding technologies are ultimately tools for pharmacists to ensure quality preparations are provided to their patients.

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CPD MULTIPLE CHOICE QUESTIONS

1. Which of the following describes the procedure of trituration?
 - A. Reduce particle size of powders
 - B. Dilute API with a powder excipient
 - C. Mixing of powders together to form an evenly distributed blend
 - D. All of the above
 - E. Both a and b are correct

2. A compounded preparation has a procedure which requires homogenisation of solids into liquids. Which technology is best for both trituration and homogenisation?
 - A. Oloid-mixer
 - B. EMP
 - C. Mortar and Pestle
 - D. Mazerustar®

3. Homogenisation has a direct impact on uniformity of content and uniformity of unit dose. Uniformity of unit dose can be assessed by weight variation test.
 - A. True
 - B. False

4. What variables are used to calculate MAWQ?
 - A. Linearity and permissible error
 - B. Readability and permissible error
 - C. Linearity and readability
 - D. Any of the above

5. Who is responsible for the quality of the compounded preparation?
 - A. Prescriber
 - B. Pharmacist
 - C. Technician
 - D. Patient