PHARMACEUTICAL AND ALLIED PRODUCTS MANUFACTURING
Demonstrate knowledge of solids processing for pharmaceutical and allied products manufacturing

level: 2
credit: 4
planned review date: May 2007
sub-field: Pharmaceutical and Allied Products
purpose: People credited with this unit standard are able to demonstrate knowledge of solids blending, granulating, solids drying, milling, and sieving for pharmaceutical and allied products manufacture.
entry information: Recommended: Unit 21367, Demonstrate basic knowledge of solid and liquid pharmaceutical and allied products manufacturing, or demonstrate equivalent knowledge and skills.
accreditation option: Evaluation of documentation by NZQA.
moderation option: A centrally established and directed national moderation system has been set up by the Competenz Incorporated.
special notes: 1 Fluid energy mills have no moving parts and include: tangential, loop, opposed jet, fluid bed, fixed or moving target. Impact mills include: hammer air swept, hammer conventional, pin/disc, cage. Screening mills include: rotating impellor, rotating screen, oscillating. Tumbling mills include: ball media, rod media, vibrating.

2 Competenz unit designation is PAMM2.2.
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Elements and Performance Criteria

element 1

Demonstrate knowledge of solids blending.

performance criteria

1.1 Eight major factors affecting blend homogeneity are identified, and the basic influence of all major factors on blend homogeneity is explained.

Range: major factors – particle size, particle shape, particle charge, particle density, particle tack, proportions of materials, blender characteristics, blending time, blending speed, head space, temperature, humidity.

1.2 Three common types of mechanical blenders and three common types of tumble blenders are identified. The basic operating principles of one common mechanical blender and one common tumble blender are described.

Range: mechanical blenders – ribbon, auger, planetary, paddle, screw; tumble blenders – intermediate bulk containers, drum, Y-cone, V-cone, double cone.

element 2

Demonstrate knowledge of granulating.

performance criteria

2.1 The common basic characteristics of granulated materials are identified and explained.

Range: basic characteristics – size, shape, appearance, friability, density, moisture content, compressibility, consistency.
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2.2 Six major factors affecting granule characteristics are identified, and the basic influence of all major factors on granule characteristics is explained.

Range: major factors – starting material characteristics, granulating solution type, granulating action, solution feed rate, machine speed, time, temperature, batch size, humidity.

2.3 Four common types of granulators are identified and the basic operating principles of two common granulators are described.

Range: granulators – planetary mixer, conventional mixer/granulator, high shear, fluidised bed, roller mills, extrusion.

**element 3**

Demonstrate knowledge of solids drying.

**performance criteria**

3.1 Eight major factors affecting drying are identified, and the basic influence of all major factors on drying is explained.

Range: major factors – solids content, moisture/solvent content, surface area, solids properties, moisture/solvent properties, temperature, airflow, humidity of drying air, air change rate, vacuum/pressure, type of drier, drying time.

3.2 Six common types of driers are identified and the basic operating principles of two common driers are described.

Range: driers – air, oven, freeze, fluid bed, vacuum, spray, forced air, centrifugal, dehumidifying, tray.
element 4
Demonstrate knowledge of milling.

performance criteria

4.1 Six major factors affecting milled particle size and shape are identified, and the basic influence of all major factors on milled particle size and shape is explained.

Range: major factors – cutter speed, cutter shape, feed rate, screen size, cutter clearances, milling action, heat, humidity, moisture content, electrostatic charge.

4.2 Four common types of mills are identified and the basic operating principles of two common mills are described.

Range: mills – fluid energy, impact, cutting, compression, screening, tumbling.

element 5
Demonstrate knowledge of sieving.

performance criteria

5.1 Six major factors affecting sieved particle size are identified, and the basic influence of all major factors on sieved particle size is explained.

Range: major factors – particle size, particle shape, vibration rate, screen size, static load, sieving time, sieve type, moisture content, electrostatic charge, humidity.

5.2 The basic meaning of particle size distribution and over and under size is explained.
5.3 Four common types of sieves are identified and the basic operating principles of two common sieves are described.

Range: sieves – manual, vibratory, air swept, reciprocating, brush type, rotary.

Comments on this unit standard

Please contact Competenz info@competenz.org.nz if you wish to suggest changes to the content of this unit standard.

Please Note

Providers must be accredited by the Qualifications Authority or a delegated inter-institutional body before they can register credits from assessment against unit standards or deliver courses of study leading to that assessment.

Industry Training Organisations must be accredited by the Qualifications Authority before they can register credits from assessment against unit standards.

Accredited providers and Industry Training Organisations assessing against unit standards must engage with the moderation system that applies to those standards.

Accreditation requirements and an outline of the moderation system that applies to this standard are outlined in the Accreditation and Moderation Action Plan (AMAP). The AMAP also includes useful information about special requirements for providers wishing to develop education and training programmes, such as minimum qualifications for tutors and assessors, and special resource requirements.

This unit standard is covered by AMAP 0134 which can be accessed at http://www.nzqa.govt.nz/site/framework/search.html.