

Specification of Competency Standards
for the Testing, Inspection and Certification Industry
Unit of Competency

Functional Area - Testing Operations

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| Title | Perform physical tests on pharmaceutical products |
| Code | 105866L4 |
| Range | This unit of competency (UoC) covers the abilities to carry out physical tests on pharmaceutical products independently by applying suitable equipment and conditions, and judge test results in testing laboratories. |
| Level | 4 |
| Credit | 2 (For Reference Only) |
| Competency | <p>Performance Requirements</p> <p>1. Possess knowledge of physical tests for pharmaceutical products</p> <ul style="list-style-type: none"> • Employ the principles and concepts underpinning physical tests for pharmaceutical products, e.g.: <ul style="list-style-type: none"> ○ hardness, ○ dissolution, ○ disintegration, ○ moisture. • Identify types of physical tests required for selected pharmaceutical products in relevant test standards / pharmacopoeia, e.g.: <ul style="list-style-type: none"> ○ British Pharmacopoeia (BP), ○ United States Pharmacopoeia (USP). • Describe the test method routinely used for performing physical test of pharmaceutical products including: <ul style="list-style-type: none"> ○ properties of pharmaceutical products under test, ○ key preparation/measurement steps in test method, ○ calculation steps to give results in appropriate accuracy, precision, units and uncertainty, ○ expected values for sample type. • Describe the operation of equipment used for physical tests of selected pharmaceutical products. • Describe the procedures for ensuring traceability of samples, test pieces, test data and results. • Apply the concepts of equipment calibration and performance check to physical tests. <p>2. Perform physical tests on pharmaceutical products</p> <ul style="list-style-type: none"> • Determine the test request and identify sample characteristics that may affect selection and application of test methods. • Apply appropriate test method, testing equipment and test conditions. • Prepare a representative portion of the laboratory sample of selected pharmaceutical product to reduce the sample complexity and eliminate matrix effects. • Carry out routine performance check of equipment according to manufacturer's instruction to ensure it is ready for physical tests on pharmaceutical products. • Set up, optimise and check the calibration status of equipment. • Carry out physical tests on the sample independently using the calibrated equipment and specified conditions. • Conduct sufficient measurements to obtain accurate and reliable test data and/or observations and judge test results against relevant specifications. <p>3. Exhibit professionalism</p> <ul style="list-style-type: none"> • Ensure all tests are carried out in compliance with good laboratory practices and relevant categories of international standards. |

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| | <ul style="list-style-type: none">• Ensure integrity and confidentiality of laboratory data and information by observing the relevant code of conduct. |
| Assessment Criteria | <p>The integrated outcome requirements of this UoC are the abilities to:</p> <ul style="list-style-type: none">• carry out physical tests on selected pharmaceutical product independently by applying appropriate test method, testing equipment and test conditions according to the requirements of test request,• record accurate test data and observations and judge test results to confirm the compliance of the pharmaceutical product against relevant specifications of test standard. |
| Remark | |