

ICS 11.040.40

CCS C45

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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0606.13-2008

**Tissue engineered medical products - Part 13: Standard test
method for automated cell counting**

组织工程医疗产品 第13部分：细胞自动计数法

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Foreword

This document was issued on 25 April 2008 by the National Medical Products Administration and takes effect on 1 June 2009.

It is a YY/T standard: it is recommended rather than compulsory, but it is the method a Chinese reviewer applies when assessing a registration submission.

It is classified under ICS 11.040.40, Chinese classification C45.

1 Scope

YY/T 0606.13 is Part 13 of the Chinese tissue engineered medical product series and covers automated cell counting. For a cell-containing product, the cell count is a release specification: it is the dose. Manual counting on a haemocytometer carries an operator-dependent variability that is tolerable in research and not in manufacture, which is what makes an automated method with a defined procedure necessary. The standard sets out how such counting is performed and validated for tissue engineered products. It is the counting counterpart of YY/T 1562 on cell viability in the same family of scaffold and cell evaluation methods. For a manufacturer of cell-based or cell-seeded products for the Chinese market, this is the method behind the cell number on the label.

About this edition

YY/T 0606.13-2008 is the current edition. It was issued on 25 April 2008 and has been in force since 1 June 2009.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up

documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

Classification and status

YY/T 0606.13-2008 is classified under ICS 11.040.40. ICS is the International Classification for Standards, the same scheme used by ISO and by the national bodies of most countries, which is what allows a Chinese standard to be placed beside its foreign counterparts on subject rather than on number.

Its Chinese Standard Classification code is CCS C45. CCS is the domestic scheme, a letter for the sector and two digits for the subject within it, and it is the code by which the standard is filed and searched in China.

The YY/T prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

YY/T 0606.13-2008 runs to 15 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

About this English translation

The English edition of YY/T 0606.13-2008 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in YY/T 0606.13-2008 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit read from the English text is the limit that will be applied by a Chinese inspection body reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect, the ICS and CCS classification. The requirements, limits, tables and test conditions are in the document itself.