

ICS 11.040.20

CCS C31

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

YY 0765.1-2009

**Single-use materials for virus inactivation of blood and blood
components - Part 1: Methylene blue virus inactivation
materials**

一次性使用血液及血液成分病毒灭活器材 第1部分：亚甲蓝病毒灭活器材

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Foreword

This document was issued on 30 December 2009 by the National Medical Products Administration and takes effect on 1 June 2011.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under ICS 11.040.20, Chinese classification C31.

1 Scope

YY 0765.1 covers the single-use materials used to inactivate viruses in plasma by the methylene blue and light method, the pathogen reduction technique used widely in Chinese blood services. Methylene blue is added to plasma, illuminated, and then removed by a filter: the dye damages viral nucleic acid, and the filter has to take the dye back out before the plasma is transfused. This standard sets the requirements for that kit and the test methods that verify them, covering the dye dose, the illumination, the removal filter and its efficiency, the effect on plasma proteins and coagulation factors, and the sterility. Being a YY standard without the /T suffix, compliance is compulsory in China.

About this edition

YY 0765.1-2009 is the current edition. It was issued on 30 December 2009 and has been in force since 1 June 2011.

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 0765.1-2009 is classified under ICS 11.040.20. 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 C31. 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 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 0765.1-2009 runs to 43 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 0765.1-2009 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 0765.1-2009 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.