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In Vitro Mammalian Cells Chromosome Aberration Test

体外哺乳动物细胞染色体畸变试验方法

National Medical Products Administration

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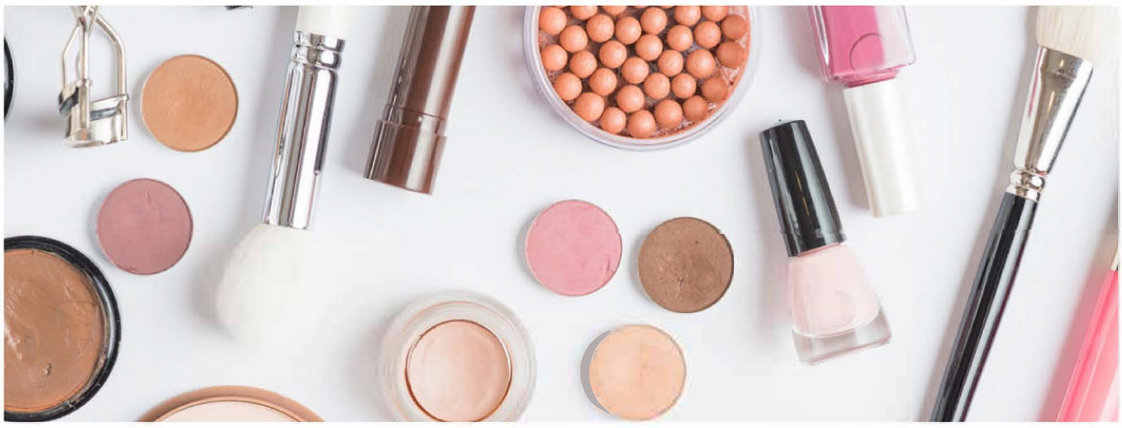
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Attachment 7

In Vitro Mammalian Cells Chromosome Aberration Test

1 Scope

This method specifies the basic principles, requirements and methods for the *in vitro* mammalian cells chromosome aberration test.

This method applies to the evaluation of the mutagenicity of cosmetic ingredients and their products.

2 Test Objectives

This test is designed to detect the chromosome aberrations in incubated mammalian cells, so as to evaluate the potential mutagenicity of test substances.

3 Definitions

3.1 Chromosome-Type Aberration

Structural damage to chromosomes, manifested as break or breakage-and-reunion alterations occurring at the identical site on both chromatids.

3.2 Chromatid-Type Aberration

Structural damage to chromosomes, manifested as break or breakage-and-reunion events on chromatids.

3.3 Chromatid Gap

A region devoid of chromatin on a single chromatid, with a width less than the cross-sectional width of the chromatid, and in which a minimal misalignment of the chromatid is present.

3.4 Chromatid Break

Discontinuity of a chromatid, characterized by the presence of a clearly asymmetrical

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附件 7

体外哺乳动物细胞染色体畸变试验方法

In Vitro Mammalian Cells Chromosome Aberration Test

1 范围

本方法规定了体外哺乳动物细胞染色体畸变试验的基本原则、要求和方法。

本方法适用于评价化妆品原料及其产品的致突变性。

2 试验目的

本试验用于检测培养的哺乳动物细胞染色体畸变，以评价受试物致突变的可能性。

3 定义

3.1 染色体型畸变 chromosome-type aberration

染色体结构损伤，表现为在两个染色单体相同位点均出现断裂或断裂重组的改变。

3.2 染色单体型畸变 chromatid-type aberration

染色体结构损伤，表现为染色单体断裂或染色单体断裂重组的损伤。

3.3 染色单体裂隙 chromatid gap

单个染色单体上出现的无染色质的区域，其宽度小于染色单体的横截面的宽度。其中存在染色单体的最小错位。

3.4 染色单体断裂 chromatid break

染色单体的不连续，其中有一条明显的不对称染色单体。

3.5 多倍体 polyploidy

整个染色体组的细胞或生物体中的染色体数目畸变，而不是单个染色质或染色体（非整倍体）。

3.6 核内复制 endoreduplication

DNA 复制的 S 期末，细胞核没有进入有丝分裂，而开始另一个 S 期的过程，其结果是染色体具有 4，8，16，…，个染色单体。

3.7 有丝分裂指数 mitotic index



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