Criteria for decorative contact lens

(April 28, 2009)
(MHLW Ministerial Announcement No. 283)

In accordance with provisions in Article 42, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the criteria for decorative contact lens shall be established as follows and applied from November 4, 2009. To decorative contact lens existing on the day of application, however, provisions of this announcement shall not be applied until February 3, 2010.

Criteria for decorative contact lens

1 Definition

A decorative contact lens (hereinafter referred to as "lens") is a contact lens that is intended to change the appearance of the iris or pupil (color, pattern, or shape) but does not have a function to correct the vision.

2 Scope of application

The concerned criteria shall be applied to a plastic lens. To lens approved under provisions in Article 23-2-5, Paragraph 1 or Article 23-2-17, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960), however, provisions in 3.6 Cytotoxicity shall not be applied.

3 Quality

1 Shape and appearance

A Lens with a water content (defined as the ratio of the weight of water contained in the lens with respect to the weight of the whole lens, hereinafter the same) of < 10%

(1) There shall be no air bubble, impurity, or change of color inside.

(2) There shall be no harmful scratch or concavity/convexity on the surface for the cornea, etc. when observed using a device to observe objects at ≥ 10 fold magnification.

(3) The edge shall be smoothly rounded and shall not have a shape that may damage the cornea, etc.

B Lens with a water content of ≥ 10%

The lens, which is made swollen until reaching a saturated state, shall meet the above criteria A (1) to (3).

2 Diameter

A Lens with a water content of < 10% (except for ones listed in B)

When the diameter is measured, the tolerance shall be within ± 0.10 mm of the indicated diameter at any site.

B Lens with a water content of < 10% and made of a highly flexible material

When the diameter is measured, the tolerance shall be within ± 0.20 mm of the indicated diameter at any site.

C Lens with a water content of ≥ 10%

When the diameter of the lens, which is made swollen until reaching a saturated state, is measured, the tolerance shall be within ± 0.20 mm of the indicated diameter at any site.

3 Thickness

A Lens with a water content of < 10%

When the thickness is measured at its center, the tolerance shall be within ± 0.02 mm of the set thickness (hereinafter referred to as "set value").

B Lens with a water content of ≥ 10%

When the thickness of the lens which is made swollen until reaching a saturated state is measured at its center, the tolerance shall be within ± (0.010 + [set value × 10%]) mm of the set value when the set value is ≤ 0.10 mm or within ± (0.015 + [set value × 5%]) mm of the set value when the set value is > 0.10 mm.

4 Base curve

A Lens with a water content of < 10% (except for ones listed in B)

When the radius of curvature of the center of the back optical surface of the lens (hereinafter referred to as "base curve") is measured, the tolerance shall be within ± 0.025 mm of the indicated base curve when it is a poly(methyl methacrylate) lens or within ± 0.05 mm of the indicated base curve when it is a lens other than poly(methyl methacrylate) lenses.

B Lens with a water content of < 10% and made of a highly flexible material

When the base curve is measured, the tolerance shall be within ± 0.10 mm of the indicated base curve.

C Lens with a water content of ≥ 10%

When the base curve of the lens, which is made swollen until reaching a saturated state, is measured, the tolerance shall be within ± 0.20 mm of the indicated base curve.

5 Vertex power

A Lens with a water content of < 10% (except for ones listed in B)

When the vertex power is measured with the back surface of the lens set toward the light source of a lens meter (which shall conform to the Japanese Industrial Standards (JIS) B 7183 under the Industrial Standardization Act [Act No. 185 of 1949], hereinafter the same), the tolerance shall be within ± 0.12D (diopter).

B Lens with a water content of < 10% and made of a highly flexible material

When the vertex power is measured with the back surface of the lens set toward the light source of a lens meter, the tolerance shall be within ± 0.25D.

C Lens with a water content of ≥ 10%

When the vertex power is measured with the back surface of the lens set toward the light source of a lens meter, after removing the water from the lens which is made swollen until reaching a saturated state, the tolerance shall be within ± 0.25D.

6 Cytotoxicity

Absence of cytotoxicity, which is a problem for use, shall be confirmed based on JIS T 0993-1.

Revised text (Excerpt) (MHLW Ministerial Announcement No. 439 of November 21, 2014)

This announcement shall be applied from the effective date of the Act Partially Amending the Pharmaceutical Affairs Act (November 25, 2014).

Supplementary Provisions (Excerpt) (MHLW Ministerial Announcement No. 48 of June 28, 2019)

(date of application)

1 This announcement shall be applied from the effective date of the Act Partially Amending the Unfair Competition Prevention Act (July 1, 2019).