

Criteria for vision corrective contact lens

(October 5, 2001)

(MHLW Ministerial Announcement No. 349)

In accordance with provisions in Article 42, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the criteria for vision corrective contact lens (MHW Announcement No. 302 of August 1970) shall be thoroughly revised as follows and applied from October 1, 2002. To products manufactured or imported until September 30, 2002, the provisions then in force shall remain applicable.

Criteria for vision corrective contact lens

1 Definition

A vision corrective contact lens (hereinafter referred to as “lens”) is a product that can correct vision when worn directly on the eye.

2 Scope of application

The concerned criteria shall be applied to a plastic lens to be worn on the surface of the cornea.

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 $\geq 10\%$

The product, 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 $\geq 10\%$

When the diameter of the product, 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 $\geq 10\%$

When the thickness of the product which is made swollen until reaching a saturated state is measured at its center, the tolerance shall be within $\pm (0.010 + [\text{set value} \times 10\%])$ mm of the set value when the set value is ≤ 0.10 mm or within $\pm (0.015 + [\text{set value} \times 5\%])$ 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 $\geq 10\%$

When the base curve of the product, 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 the values in the right column of the table shown below according to the category of vertex powers indicated in the table.

D: diopter

Vertex power indicated (D)	Tolerance (D)
0 to ± 5.00	± 0.12
More than ± 5.00 to ± 10.00	± 0.18
More than ± 10.00 to ± 15.00	± 0.25
More than ± 15.00 to ± 20.00	± 0.37
More than ± 20.00	± 0.50

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 the values in the right column

of the table shown below according to the category of vertex powers indicated in the table.

Vertex power indicated (D)	Tolerance (D)
0 to ± 10.00	± 0.25
More than ± 10.00	± 0.50

C Lens with a water content of $\geq 10\%$

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 product which is made swollen until reaching a saturated state, the tolerance shall be within the values in the right column of the table shown below according to the category of vertex powers indicated in the table.

Vertex power indicated (D)	Tolerance (D)
0 to ± 10.00	± 0.25
More than ± 10.00 to ± 20.00	± 0.50
More than ± 20.00	± 1.00

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).