

BIOLUTEIN® Quality Assurance

BioLutein® is processed using our large-scale extraction facility using only handpicked marigold flowers. Our strict quality check process and procedures ensure every lot of BioLutein® is safe and strictly adhere to global standards and specifications.

Specification (ex: Lutein soft Extract 20% (F))

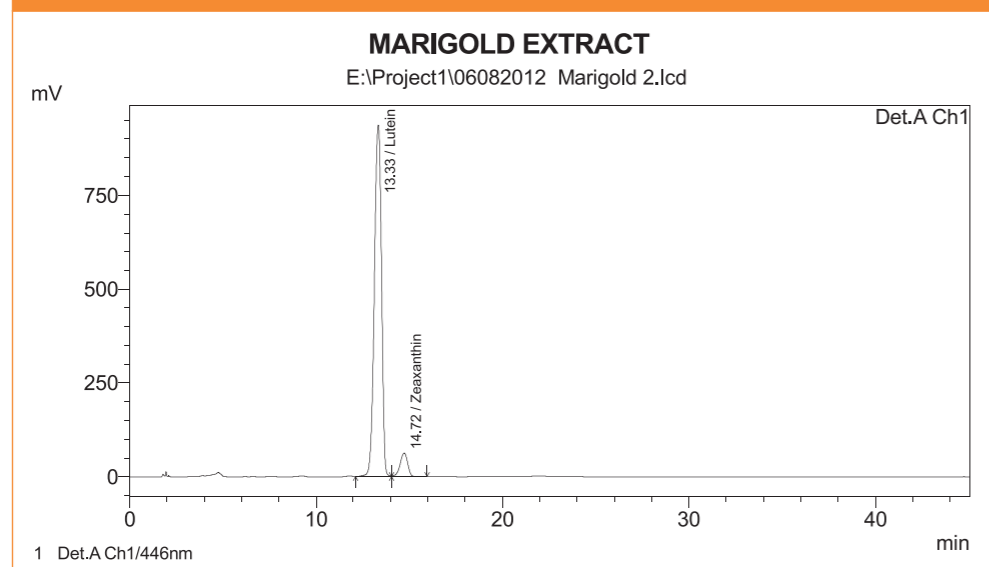
Description	: Brownish red color viscous liquid with characteristic odor
Identification	: HPLC
Solubility	: Soluble in oil
Heavy Metal	: Not more than 20ppm
Arsenic	: Not more than 1ppm
Lead	: Not more than 10ppm
Assay by HPLC	
Content of Lutein	: Not less than 20%
Zeaxanthin	: Not less than 1%
Ethoxyquin, TBHQ, BHT	: Should be absent
Microbiological Profile	: As per JPN food regulation



BIOLUTEIN® Available Grades:

1. 20% Free type Lutein standardized with minimum 1% Zeaxanthin (powder and soft extracts)
2. 40% Free type Lutein standardized with minimum 2% Zeaxanthin (powder)
3. 40% Ester type Lutein (powder)
4. Marigold Petal Powder (poultry and feed grade)
5. Marigold Powder standardized with 2% xanthophylls (poultry and feed grade)

HPLC test confirmation for content of Lutein and Zeaxanthin



BIOLUTEIN®



BIO ACTIVES JAPAN CORPORATION

2-15-9-9F, Kita-otsuka Toshima-ku, Tokyo 170-0004 Japan
TEL: +81-3-5981-0601 / FAX: +81-3-5981-0602
E-mail: info@bioactivesjapan.com <http://www.bioactives.co.jp/>

The statements and product shown here have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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BIOLUTEIN®

BIO ACTIVES JAPAN CORPORATION



Contracted GACP Cultivation

- Over 5000 acreage area of land under contract cultivation.
- 100% monitored cultivation & harvesting process.
- Application of natural fertilizers and manures.
- Traceability of seeding material, cultivation region, harvesting conditions, processing details using real time Cropex technology.

1



Self Fermentation Facility

- Carefully handpicked flowers to retain the seeds.
- Dedicated flower processing facility.
- Flowers washed and ensilaged for several weeks to enhance content of carotenoids.
- Washed and dried in controlled conditions and temperature to retain high lutein content.

2

BIOLUTEIN® PRODUCTION PROCESS

SEED TO SHELF TRACEABILITY SYSTEM

BIOLUTEIN®

- Dedicated ISO certified botanical extraction facility.
- Proprietary manufacturing process under controlled temperature and pressure conditions.
- Process free from organic solvents.
- Custom blends, granulations, water dispersions upon request.

ISO Certified Manufacturing



- Every lot is tested for active principle-lutein and standardized to customer specifications.
- Analysis for Heavy Metals, Aflatoxins, Pesticides, Physical analysis, Microbiological analysis and shelf-life stability.
- Safety data meeting OECD guidelines upon customer request.

Quality Check and Analysis



MARIGOLD

Marigold, belongs to the family of Asteraceae, which is a native of Central and South America, especially Peru.

Three species, *Tagetes erecta* (African marigold), *T. patula* (French marigold) and *T. tenuifolia* (Striped marigold), are the most commonly cultivated variety.

Marigold is the most viable source for various types of carotenoids which have immense medicinal properties.

INDIAN Marigold

1. Marigold flowers (*Tagetes erecta*) were recognized in India from 400 BC for their beauty and the medicinal properties.
2. Cultivated all over India for both medicinal and decoration purposes.
3. Marigolds are one of the most widely cultivated flower crops in India with an estimated cultivation area of 13,000 hectares with annual production of more than 200,000 ton of flowers, the highest for any flower grown in India.
4. India accounts for over 30 percent of global Marigold production.

Clinical Indications



Age-related macular degeneration & Cataract

1. Age-related macular degeneration (AMD) can be prevented by increase in macula pigmentation due to lutein intake.
2. A recent clinical study demonstrates that lutein supplementation increases macular pigment optical density and visual acuity in patients with age-related macular degeneration.
3. Improvement of retinal function in early age-related macular degeneration after lutein and zeaxanthin supplementation has been clinically proven. Lutein supplementation in a human subjects improved contrast sensitivity and retinal sensitivity.
4. Diets rich in lutein and zeaxanthin are associated with decreased prevalence of nuclear cataract in older women.
5. Lutein promotes optimal visual function and decrease risk for AMD and cataracts

1. Double-masked, placebo-controlled, randomized trial of lutein and antioxidant supplementation in the intervention of atrophic age-related macular degeneration: the Veterans LAST study (Lutein Antioxidant Supplementation Trial). Richer S, Stiles W, Statkute L, Pulido J, Frankowski J, Rudy D, Pei K, Tsipursky M, Nyland J. . *Optometry* 2004, 75 (4): 216-30.
2. Effects of lutein supplementation on macular pigment optical density and visual acuity in patients with age-related macular degeneration. Weigert G, Kaya S, Pemp B, Sacu S, Lasta M, Werkmeister RM, Dragostinoff N, Simader C, Garhöfer G, Schmidt-Erfurth U, Schmetterer L. 2011, *Invest Ophthalmol Vis Sci.*;52 (11):8174-8.
3. Improvement of Retinal Function in Early Age-Related Macular Degeneration After Lutein and Zeaxanthin Supplementation: A Randomized, Double-Masked, Placebo-Controlled Trial. 2012, Ma L, Dou HL, Huang YM, Lu XR, Xu XR, Qian F, Zou ZY, Pang HL, Dong PC, Xiao X, Wang X, Sun TT, Lin XM. *Am J Ophthalmol.* 2012 Jul 24. [Epub ahead of print]
4. Associations between age-related nuclear cataract and lutein and zeaxanthin in the diet and serum in the Carotenoids in the Age-Related Eye Disease Study, an Ancillary Study of the Women's Health Initiative. Moeller SM, Voland R, Tinker L, Blodi BA, Klein ML, Gehrs KM, Johnson EJ, Snodderly DM, Wallace RB, Chappell RJ, Parekh N, Ritenbaugh C, Mares JA; CAREDS Study Group; Women's Health Initiative. *Arch Ophthalmol.* 2008 Mar;126(3):354-64.
5. Dietary supplementation: effects on visual performance and occurrence of AMD and cataracts, Barker Fm, 2nd (2010). *Current medical research and opinion,* 26 (8): 2011-23.

Healthy Skin Conditions

6. Clinically lutein has been shown to promote hydration and skin elasticity. It also increases the levels of superficial skin lipids. Lutein offers protection to the skin from daily detrimental exposure to UV rays and pollutants in air by scavenging the harmful free-radicals. Marigold extracts rich in lutein showed highest DPPH radical scavenging activity. They were also effective against lipid peroxidation and hydroxyl radical scavenging activities with maximum reducing power.
6. Beneficial long-term effects of combined oral/topical antioxidant treatment with the carotenoids lutein and zeaxanthin on human skin: a double-blind, placebo-controlled study. Palombo P, Fabrizi G, Ruocco V, Ruocco E, Fluhr J, Roberts R, Morganti P. *Skin Pharmacol Physiol.* 2007;20(4):199-210.

