GENOSCAN BIOSCIENCES LIMITED

Egg-derived IgY ingredient

Freeze-dried hyperimmune egg-yolk IgY powder, specified by IgY content and by antigen-specific ELISA titer, for dietary supplement manufacturers.

10%
w/w IgY, standard grade (200 mg per 2 g)

>80%
w/w available by further purification

≥1:10,000
typical ELISA titer, per antigen

36 mo
shelf life, sealed

Genoscan Biosciences Limited · Richmond, BC, Canada · info@genoscanbio.com · genoscanbio.com

Specification

Freeze-dried egg-yolk IgY (immunoglobulin Y) powder from hens immunized with defined recombinant antigens. The antigen panel is disclosed under NDA.

Parameter	Specification	Method
Appearance	Light yellow to yellow powder	Visual
IgY content	Standard grade: 200 mg IgY per 2 g powder (about 10% w/w). Custom grades on request, up to above 80% w/w after further purification.	ELISA
Antigen-specific IgY	Reported per antigen on each lot COA. Typical value: end-point titer ≥1:10,000 against one reference antigen; titers differ between antigens. The end point is the highest dilution giving a signal at least 2× the blank control.	ELISA
Total protein	≥90% (standard grade)	Coomassie Brilliant Blue (Bradford) assay
Moisture	≤2%	USP <731> Loss on Drying
pH	6.0 to 7.5, measured on the aqueous extract before freeze-drying	USP <791> pH
Total plate count	<1,000 CFU/g	USP <2021>
Pathogens	Negative: *E. coli*, *Salmonella*, *Staphylococcus aureus*	USP <2022>
Allergen	Contains egg	Declaration
Shelf life	36 months, sealed. Antigen-specific titer after 3 years is at least 95% of the initial value.	Real-time stability, ELISA
Storage	Cool, dry place. Refrigeration preferred. Normal ambient up to 35 °C. Do not exceed 50 °C.	–

Physicochemical and microbiological tests follow United States Pharmacopeia (USP) methods and are performed by Eurofins. The method reference is printed on each lot COA.

Supply terms

Term	Detail
Packaging	500 g foil bag; 10 kg carton. OEM/ODM packaging on request.
Minimum order	Bulk powder: 50 kg. Finished product (OEM/ODM): 60,000 capsules or 1,000 bottles.
Lead time	4 to 6 weeks after deposit and formula confirmation
Samples	Available for evaluation

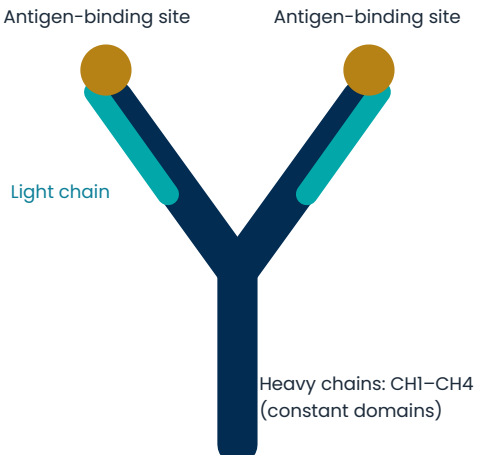
Understanding IgY powder

A short technical note for formulation and R&D teams. It describes the ingredient and makes no claims about finished products.

What IgY is

IgY is the main antibody in avian blood and egg yolk. Hens transfer it into the yolk, so eggs are a practical, non-invasive source. It is a Y-shaped antibody of about 180 kDa with two heavy and two light chains. Compared with mammalian IgG:

- The heavy chain has four constant domains (CH1 to CH4), not three.
- The hinge region is shorter and less flexible.
- It does not bind protein A or G as IgG does, which matters for purification and assay design.



Schematic of IgY. Not to scale.

Two numbers, two different questions

IgY content (% w/w)
How much IgY is in the powder, regardless of what it binds. Standard grade is 10% w/w; higher grades are available.

Antigen-specific titer (ELISA)
How much of that IgY binds a particular antigen. Reported per antigen; a titer for one antigen says nothing about another.

When comparing suppliers, ask for both numbers, the assay format and the antigen used.

How the ingredient is made

1. **Antigen design.** Defined recombinant antigens are selected (panel under NDA).
2. **Immunization.** Laying hens are immunized on a schedule.
3. **Collection.** Eggs are collected and the yolk is separated.
4. **Extraction.** IgY is extracted from the yolk to the target grade.
5. **Freeze-drying.** The extract is dried to a powder with moisture of 2% or less.
6. **Release testing.** Each lot is tested against specification and reported on a COA.

Stability and formulation

IgY is a protein, so formulation choices affect how much intact, active antibody a finished product delivers.

- **Acid.** Published work reports IgY is relatively stable between pH 4 and 11 but loses activity at lower pH, and that pepsin sensitivity depends on pH and enzyme ratio [1,2]. Protective approaches such as enteric capsules or encapsulation are commonly used [3].
- **Heat.** Published work reports minimal loss at 60 to 65 °C and a marked drop after 15 minutes at 70 °C or above [1]. Avoid high-temperature steps after the IgY is added.
- **Moisture.** Like most freeze-dried proteins the powder is hygroscopic. Keep it sealed and handle it in low humidity.
- **Verification.** Test antigen-specific activity in your finished dosage form, not only in the raw powder.

Working with Genoscan

Customization

- Antigen selection or panel, details under NDA
- IgY content grade
- Format: bulk powder, capsule, chewable, sachet
- Packaging and labeling for your brand

Documents on request

- Certificate of Analysis, per lot
- Ingredient specification sheet
- Safety Data Sheet (SDS)
- Pathogen test reports
- Allergen declaration (egg)
- GMP certificates of manufacturing partners (under NDA)
- Real-time stability data
- HS code and tariff classification

Handling and allergen

Derived from eggs; declare egg as an allergen on finished-product labels. Store sealed in a cool, dry place; refrigeration gives the best retention of activity.

Manufacturing

Produced at cGMP-certified contract manufacturing facilities. Genoscan works with more than one qualified partner; facility names and certificate scope are disclosed under NDA.



Freeze-drying equipment (illustrative image).

Regulatory note

This ingredient is supplied for the manufacture of dietary supplements and is not for direct sale to consumers. Requirements differ by market (for example US DSHEA and FDA labeling rules, Health Canada NPN licensing). Brand owners are responsible for the finished product's formulation, labeling and claims. This document is technical information, not legal or regulatory advice.

Request a sample, spec sheet or COA
info@genoscanbio.com · genoscanbio.com · Genoscan Biosciences Limited, Richmond, BC, Canada

References

1. Kovacs-Nolan J, Mine Y. Egg yolk antibodies for passive immunity. Annu Rev Food Sci Technol. 2012;3:163-182.
2. Shimizu M, Nagashima H, Sano K, Hashimoto K, Ozeki M, Tsuda K, Hatta H. Molecular stability of chicken and rabbit immunoglobulin G. Biosci Biotechnol Biochem. 1992;56(2):270-274.
3. Wang H, Zeng X, Lin J. Ex vivo evaluation of egg yolk IgY degradation in chicken gastrointestinal tract. Front Immunol. 2021;12:746831.