MACSEN LABS

APIs • Specialty & Fine Chemicals • Dyes

GMP Certified

GMP Audited Australia

US-FDA Registered & Compliant

WHO-GMP & EU-WC Certified

PMDA Audit Ongoing

World's only cGMP manufacturer of a complete range of Pharmaceutical Dyes

About Macsen Labs

Macsen Labs (N.K Agrawal) Group, is a chemical manufacturing organization with its origin dating back to 1952. We have expertise in manufacturing APIs in the cGMP environment and in compliance with international pharmaceutical guidelines like ICH, WHO-GMP, and US FDA 21 CFR. Our proficiency extends to performing process validations, method validations, detailed impurity profiling, impurity characterization, risk assessment of carcinogenic/mutagenic impurities, elemental impurities, and preparing DMFs. We also have a state-of-the-art R&D setup with the latest high-tech instruments like LC-MS/MS, GC-MS/MS & ICP MS.

Our APIs

Methylene Blue USP/BP/EP
Methylthioninium Chloride
USDMF (Completeness Assessment Done)
EU-WC | CEP - Available soon

Fluorescein Sodium USP/BP/Ph Eur
USDMF | EU-WC & CEP - Available soon

Selenious Acid USP
USDMF

Indocyanine Green USP
Validation Completed | USDMF & EU-WC - Available soon

Trypan Blue
USDMF & EU-WC - Available soon

Silver Nitrate USP/BP/IP
USDMF & EU-WC - Available soon

Indigo Carmine USP
USDMF - Available soon

Silver Sulfadiazine USP
USDMF | EU-WC | JDMF - Available soon

Selenium Sulfide USP
USDMF | EU-WC - Available soon

Acriflavine Hydrochloride/Neutral

Gentian Violet
USDMF & EU-WC - Available soon

Lanthanum Carbonate

Merbromin/Mercurochrome

Proflavine Hemisulphate BP/IP

Deferiprone BP/EP

Nicorandil BP/EP/IP

New APIs - Launched in 2023

Brilliant Blue G
Viloxazine Hydrochloride

APIs Under Development

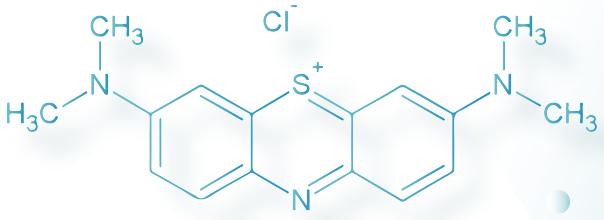
Isosulfan Blue
Amylmetacresol
Levomefolate Calcium
Ciclopirox Olamine
Quinfamide
Colloidal Silver
Erdosteine
Sodium Tetradecyl Sulfate

Pharmaceutical dyes hold a huge significance in the pharma industry.

They are employed in a wide variety of applications including as therapeutic agents, diagnostic agents, photosensitizers, fluorophores in in-vivo imaging, light-activated anticancer/antimicrobials, in angiography, as markers during surgical procedures to enhance visualization, etc.

Methylene Blue

A multifaceted versatile dye with numerous existing medical applications and a range of emerging uses.



Different functions of methylene blue

- A strong antioxidant
- A disinfectant
- Capable of repeated redox cycling
- Can cross the blood-brain barrier
- Mitochondrial function enhancer
- Light-activated potent broad-spectrum antimicrobial agent (Photosensitizer)

Approved Pharmaceutical Applications

For acquired methemoglobinemia

Methylene Blue, approved by the USFDA for treating acquired methemoglobinemia, counteracts oxygen deficiency in cells by converting excess methemoglobin to hemoglobin, enhancing oxygen delivery.

In Dysuria and reoccurring bladder infections

Methylene blue, a mild antiseptic, numbs urinary tract mucous membranes, easing UTI symptoms like discomfort and frequent urination.

Antidote for cyanide and ifosfamide poisoning

Methylene blue reduces cyanide toxicity by restoring oxidation-reduction equilibrium and Ca2+ channel function. It is also used to treat ifosfamide neurotoxicity.

In Septic Shock

It works by inhibiting the nitric oxide-cyclic guanosine monophosphate pathway, which is active during a septic shock.

Applications currently under Research

Alzheimer's

Anti-aging benefits

Malaria

Cancer

Bipolar Disorder

Photodynamic Therapy

COVID-19

Catecholamine Refractory Vasoplegia

Hutchinson-Gilford Progeria Syndrome

Other General Applications

- Biological Stain or Dye
- In Aquaculture
- Redox Indicator
- Disinfectant

Macsen has been manufacturing Pharmaceutical grade Methylene Blue since the last 40 years

Our manufacturing process is non-infringing and patented.

The Indian patent office has granted us a patent, titled - “Novel Improved Methods of Synthesizing Diaminophenothiazine Compounds". Patent pending in the United States.

Manufacturer of both:

USP and EP grades with complete documentation (DMF/ ASMF).

US-DMF Filing

Our US-DMF is filed along with the successful closure of the completeness assessment review.

EU-GMP

Written Confirmation available

ASMF

Filed in Belgium, Australia & UK

CEP

Under process and will be available soon

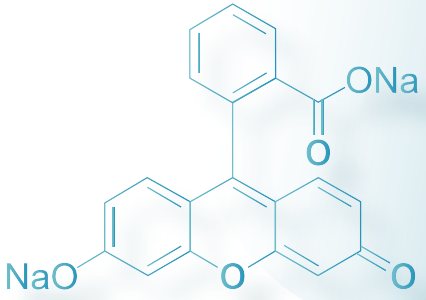
DMF

Filing in China is currently in progress.

In-house R&D support for any customizations required as per formulation specifications.

Fluorescein Sodium

Fluorescein Sodium is an essential dye in ophthalmology and diagnostics, renowned for its fluorescent properties and diverse applications.



Medical & Diagnostic Applications:

Ophthalmology

It detects damage to the cornea, such as abrasions and ulcers, and reveals tear film breakup and areas of dryness on the cornea by staining the affected areas. It also helps assess the fit of contact lenses.

Angiography

It involves injecting fluorescein into the bloodstream to highlight the blood vessels in the retina and choroid during imaging, and is used to diagnose diseases like diabetic retinopathy, macular degeneration, and retinal vessel occlusions.

Bioimaging

Fluorescein sodium is used in bioimaging to stain cells and tissues, visualize vascular flow, and track molecular interactions with high fluorescence.

Other Applications:

- As a Water Tracer
- In Biological & Biochemical Research
- In Antifreeze and Coolants

Macsen has been manufacturing Pharmaceutical grade Fluorescein Sodium since the last 40 years

Our manufacturing process is non-infringing and patented.

The Indian patent office has granted us a patent, titled - “Process for the preparation of crystalline fluorescein Sodium from diacetyl fluorescein or Fluorescein".

Manufacturer of both:

USP and BP grades with complete documentation (DMF/ASMF).

US-DMF

Filed; DMF no. is 038960.

DMF

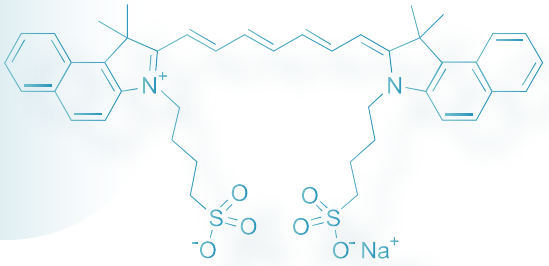
Filing is in progress in China.

EU-GMP

Written Confirmation

CEP

Under process and will be available soon.



Indocyanine Green

Indocyanine Green (ICG) is a near-infrared dye used in medical imaging to visualize blood flow and cardiac output.

Uses of Indocyanine Green:

Indocyanine green angiography

ICG angiography is used to image the choroidal blood vessels in the eye, helping diagnose and monitor conditions like macular degeneration, choroidal neovascularization, and other retinal diseases.

Capsulorhexis

It is used in cataract surgery to help remove the lens capsule.

Indocyanine green lymphography

ICG lymphography is an emerging imaging technique used to visualize lymphatic vessels and map their course as they drain to sentinel lymph nodes.

Cardiac Output Monitoring

ICG is used to measure cardiac output, hepatic function, and liver blood flow by monitoring the dye's dilution in blood over time.

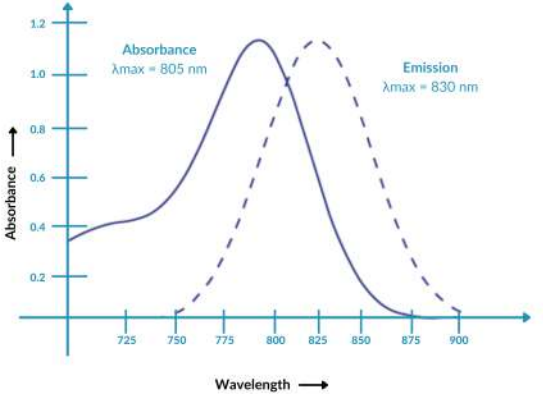
The approximate timeline for USDMF and EU-WC availability is August 2024.

Other Uses

- Perfusion diagnostics of tissues and organs
- Sentinel lymph node biopsy while undergoing tumor removal with ICG
- Selectively over-heating cells (especially cancer)

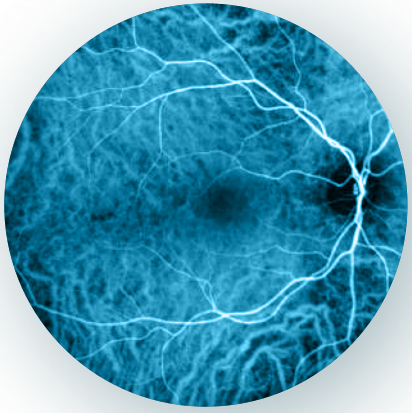
We have expanded our product line to include the manufacturing of sodium iodide-free Indocyanine Green equivalent to Infracyanine Green®, whose primary use is for patients allergic to iodine.

Indocyanine Green Absorption & Emission Spectrum

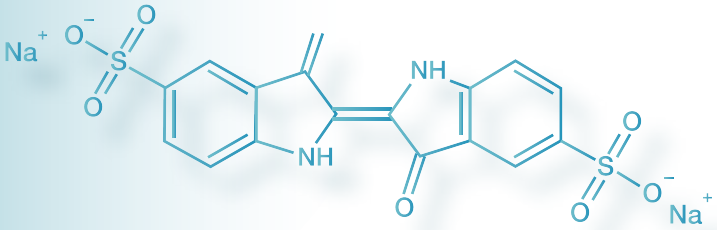


ICG has a peak absorption in the near-infrared region of the light spectrum, typically around 780-800 nm and emits fluorescence in a slightly longer wavelength, typically in the range of 820-840 nm.

Indocyanine Green Angiography vs Fluorescein Angiography



Indocyanine Green Angiography(ICGA)	Fluorescein Angiography(FA)
ICG dye has a high protein binding capacity (about 98%) and thus can image the choroidal vasculature better than fluorescein angiography.	Sodium Fluorescein dye has less protein binding capacity.
The fluorescence efficiency of the ICG molecule is less (only 4% of that of sodium fluorescein).	The fluorescence efficiency of sodium fluorescein is higher.
To detect ICG fluorescence, charge-coupled device (CCD) cameras with a digital acquisition process are necessary.	In FA, cameras with photographic films are used.
USES:- Detection of Choroidal neovascularization, Capsulorhexis, Tissue and organ circulation diagnosis, Navigation for tumors in Sentinel Lymph node Biopsy, etc.	Uses: Macular edema, Diabetic Retinopathy, Macular degeneration, Ocular melanoma, etc.



Indigo Carmine

Indigo Carmine, also known as 5,5'-Indigodisulfonic Acid Sodium Salt, is a distinctive blue dye for visualizing urological structures, aiding in surgical procedures and diagnostic evaluations.

Diagnostic & Medical Applications:

Urology

Indigo Carmine is used in Cystoscopy and Ureteroscopy and for the detection of Urinary Fistulas.

Gynecology

It assists in identifying blockages in the fallopian tubes during fertility surgeries. It also helps in the diagnosis of Amniotic Fluid Leaks, when injected intravenously.

Colorectal Surgery

Indigo Carmine is used to assess bowel perfusion during surgery.

Endoscopy

It is applied topically during endoscopic procedures to enhance visualization of the mucosal surface, aiding in the detection of abnormal areas or lesions.

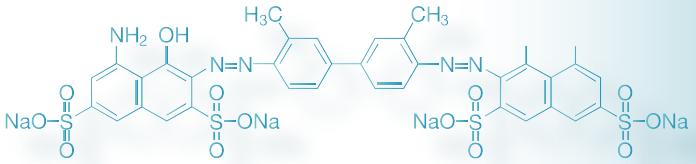
Research & Laboratory Uses

- pH indicator
- Redox Indicator
- Food coloring agent
- Testing of Kidney function

Our USDMF submission is scheduled for April 2024. EU-WC will be available by June 2024.

Trypan Blue

Trypan Blue is an azo dye for identifying viable cells, widely used in cytology and tissue staining for research and diagnostics.



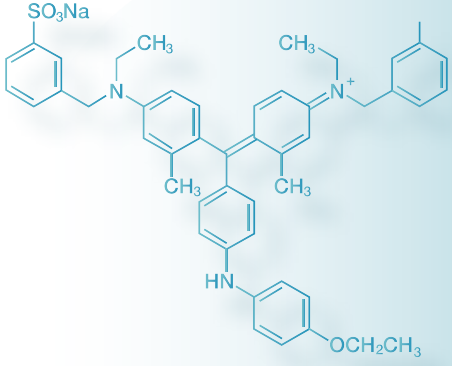
Applications

- Cell viability Assays
- In histology, for tissue staining
- Ophthalmic cataract surgery
- Antiparasitic agent
- In Vitreoretinal surgery
- Detecting Cell Membrane Integrity
- Rapid detection of Cerebrospinal fluid sterility

We are about to commercialize Trypan Blue in Macsen Drugs, our USFDA-registered API manufacturing facility in the April-June quarter of 2024. Once the commercial validation is completed, the USDMF submission is anticipated within six months.

Brilliant Blue -G

Brilliant Blue G is a synthetic dye belonging to the triphenylmethane family, widely used in biochemistry and molecular biology for various analytical purposes.



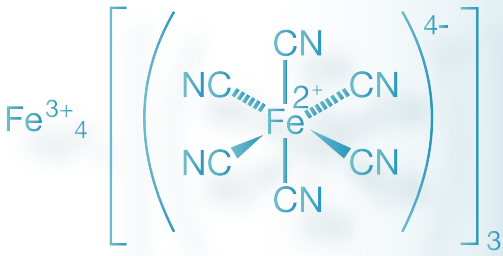
Applications

- Staining of the Internal Limiting Membrane (ILM) in vitreoretinal surgery
- Selective Neuronal Staining
- Protein Staining in SDS-PAGE (sodium dodecyl sulfate-polyacrylamide gel electrophoresis)
- Selective staining in histological and cytological samples

The product is currently in the advanced stages of development in the R&D it is expected to commercialize in 2024.

Prussian Blue

Prussian Blue is an antidote for heavy metal poisoning and a dye, with applications in histology and radiology



Medical Applications:

Heavy Metal Poisoning Treatment

Prussian Blue is approved by the USFDA as an antidote for heavy metal poisoning, such as that caused by Thallium(I) and radioactive isotopes of Caesium.

Other Applications

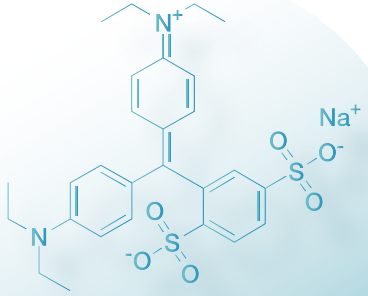
- Histopathology stain
- Electrode material in ion batteries
- Pigment
- Cyanide Photography

Prussian Blue is currently in the primary stages of development with Macsen's R&D team with an approximate development timeline of 6 months to a year.

Macsen is also working on a reduced and sodiated form of Prussian Blue called Prussian White, currently being researched for its application as a cathode material in sodium-ion batteries. For Prussian White, Macsen is already in advanced stages of development, wherein we are close to the stage of a commercially buyable product.

Isosulfan Blue

Isosulfan Blue, also known as Lymphazurin, is a visual lymphatic imaging agent used primarily in medical diagnostics.



Applications:

- Sentinel Lymph Node Mapping - Breast Cancer,
- Melanoma, and other Cancers
- Diagnosing and Mapping Lymphedema
- Lymphography - Visualizing Lymphatic System

Isosulfan Blue is currently in the primary stages of development with Macsen's R&D team, with an estimated development timeline of one year.

Fluorophores for in-vivo Imaging

Fluorophores, used in the fields of biochemistry, molecular biology, and medical diagnostics, are fluorescent photoreactive molecules that can re-emit light upon light excitation. They play a crucial role in in-vivo imaging, the non-invasive visualization of living organisms for research or diagnostic purposes.

Fluorophores can be attached to antibodies, peptides, or small molecules that specifically bind to particular targets, such as proteins, nucleic acids, or other cellular components. These conjugated fluorophores can be detected with high sensitivity due to the bright fluorescence they emit upon excitation, allowing for the precise visualization of specific biological molecules or processes within the complex environment of a living organism.

Also, advancements in fluorophore technology, particularly the development of near-infrared (NIR) fluorophores, have significantly improved the capacity for deep tissue imaging.

Macsen is already into the manufacturing of fluorophore dyes such as Fluorescein Sodium, Methylene Blue, Indocyanine Green, and Indigo Carmine which are FDA-approved for in-vivo applications. We are actively broadening our collection of fluorophores and dyes designed for in-vivo imaging applications, aiming to enhance our offerings in this area.

Macsen Images

For a complete list of products, scan the QR code

Visit us at www.macsenlab.com

Email - sales@macsenlab.com Contact: +91-72968-66111

Corporate Headquarters

303, 3rd Floor, Shivam Residency, Durga Nursery Road, Udaipur,
Rajasthan, India 313001

Sales Office

317, Marathon Max, Goregaon Mulund Link Road,
Mulund West, Mumbai 400-080

Factory Unit

Unit 1
F-261,262,263, RIICO Industrial Area, Gudli, Udaipur, Rajasthan, 313024, India.

Unit 2
Amba Mata ki Ghati, Village Titerdi, Tehsil - Girwa, Udaipur, Rajasthan, 313002, India.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N.K SYNTHESIS