

About GPC

“Our capacity has gone from local to global.”



We were founded in 2008, Lund Sweden.



We offer excellent representative and compliance management services globally.



8 offices worldwide & 2 laboratories



Today, we have more than 1500 happy clients worldwide, 99% retention rate.

Services



We have an elaborate portfolio of 15,000+ substances.



Authoring a large portfolio of 5,000+ REACH and 500+ CLP compliant SDS and e-SDSs in 30+ languages.



750+ Lead registration & consortia management.

“

We have followed our clients to new countries and markets which has made us expand our business and knowledge capacity worldwide.

”

BIS Certification Scheme: Knowing your compliance obligations



Dr. Shilpa Narang

Job title: Regulatory Affairs Manager

Global Product Compliance (GPC)-
India

Email: shilpa@in.gpcregulatory.com

Summary of Topics

- Introduction (Basic Concept of BIS, Purpose/Objective of BIS)
- Indian Standards versus BIS certification
- Process of Registering Chemicals under BIS for Indian Manufacturers /Overseas Exporters
- Requirements for submission to BIS
- Factory inspection
- Authority Fee for BIS certification, Timeline and Validity of certificate
- Compliance strategies

Introduction of BIS

- National Standard Body of India established for the harmonious development of the **standardization activities, marking and certification of goods**
- It was established under BIS Act 2016
- **Major Activities of BIS are:** Standard Formulation, Marking and certification, Hall Marking Scheme, Sale of Indian Standards, Laboratory Services, Laboratory Recognition Scheme

Purpose/Objective of BIS

Through standardization, certification and testing, BIS provides benefits to the national economy by:

- Providing safe, reliable and quality goods
- Minimizing health hazards to consumers
- Protecting the environment
- Promoting exports and imports substitute
- Controlling proliferation of varieties, etc



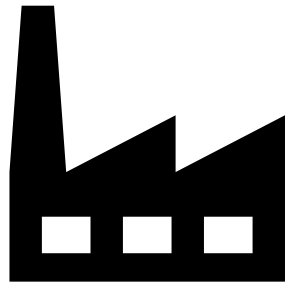
Why BIS Registration

- BIS certification is a means for providing third party guarantee of quality, safety, and reliability of products to the customers.
- Products under compulsory certification cannot be manufactured or imported to India without the standard mark.
- All the products under compulsory certification need to have standard mark before they come to Indian market for consumers.

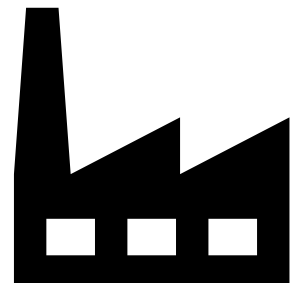
Indian Standards vs BIS certification

- **The document published by the BIS**, with regards to any article or process that is indicative of the quality and specification of the article or process
 - **Acts like a guide for the manufacturers**
-
- One can only apply for BIS registration against a particular Indian standard.
 - To apply for BIS registration, the standards should be under compulsory or voluntary certification.
 - In case of any product or chemical that has no available Indian standard for it, or the standard is under voluntary certification, the product may be exempted from BIS registration

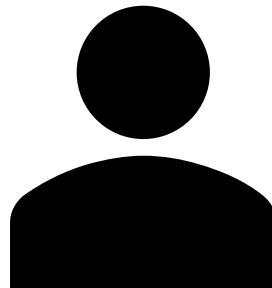
Who can apply for BIS Certification?



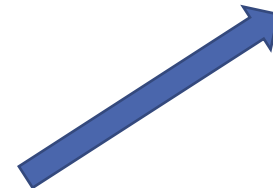
Indian Manufacturers



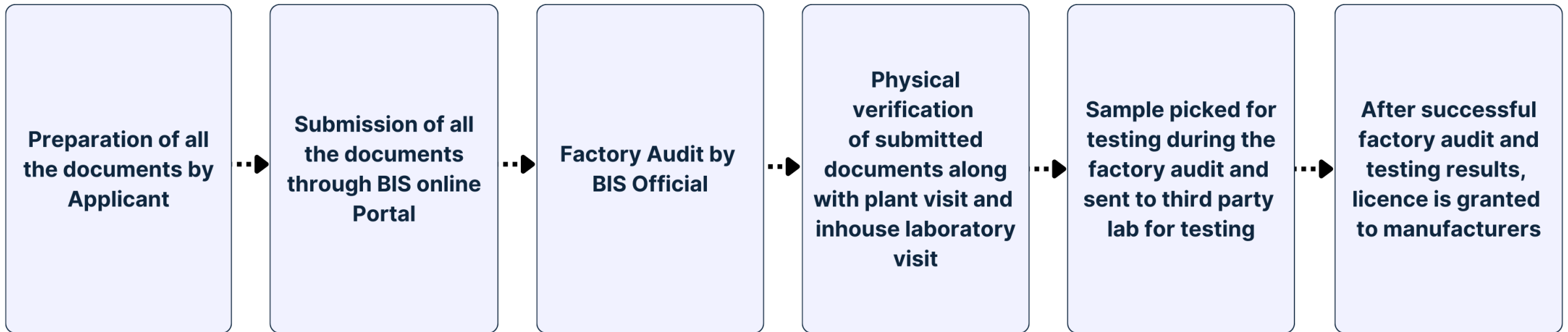
Oversea Manufacturers



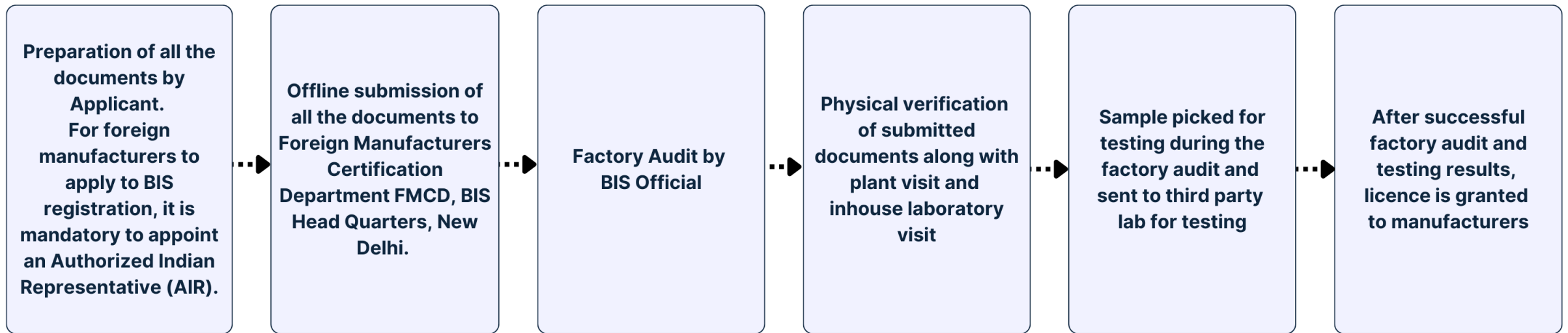
Authorized Indian Representative (AIR)
appointed by foreign manufacturers



Process of Registration (India Companies)



Process of Registration (Overseas Companies)



Requirements for BIS submission

- **Administrative documents** like Application form; Factory Name and address; Factory License; Factory Map and location; Quality control personnel details and appointment letter; Management details etc.
- **Technical documents** like in-house test report; testing equipment details; calibration certificates for all instruments; Plant machinery details; Process flow chart; Quality Manual

Factory inspection

- Chemicals need to have purity level as mentioned in the applicable BIS standard and they need to be tested as per the test methods given in the standard. In case the test methods are different, manufacturer should align his test methods as per the details mentioned in the standard.
- Manufacturer should be able to present in front of BIS official all the original documents as submitted during application submission. In case documents are written in other languages other than English, English translation of such documents is required.

Cost and Timeline

BIS application fee	1000 INR
Audit visit charges	7000 INR
Marking fee	As applicable.
Testing fee	As applicable
Annual License fee	1000 INR
Renewal application	1000 INR
Renewal Audit charges	7000 INR
Renewal Testing charges (where required) & Marking fee	As applicable at that time
Bank Guarantee-Only for foreign manufacturers	10000 USD

Timeline and Validity

- Timeline to get BIS registration certificate under Scheme I is 3-4 months for Indian Manufacturer and about 6 months for foreign manufacturer. This timeline may vary if some query arises at the time of submission or at the time of testing.
- The License is initially granted for not less than 1 year and up to 2 years. After which license needs to be renewed for not less than 1 year and up to 5 years.

Products under compulsory certification

BIS Certification Scheme I	BIS certification Scheme II
Also known as the ISI scheme, a licensing scheme.	A compulsory registration scheme.
Factory audit is mandatory.	Factory audit is not required.
There is a list of 381 products given by BIS which are covered under scheme I, which includes chemicals, steel, automobile parts, etc.	It is applied to electronic and IT products like mobiles, adaptors, batteries, etc.
It is a quality and safety assurance certification.	It is a safety certification for products coming to Indian Markets.
Mode of application is online for Indian Manufacturers and offline for foreign manufacturers.	Application process is online for Indian as well as foreign manufacturers.



Chemicals under BIS: Mandatory List (Scheme I) (1)

	IS No.	Product	Date of implementation
1	IS 252:2013	Caustic Soda –Specification	2018-04-03
2	IS 15573	Poly Aluminium Chloride	2020-02-05
3	IS 14887:2014	Textiles –High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for packaging of 50 kilogram Foodgrains	2020-10-24
4	IS 16208:2015	Textiles –High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for packaging 10 kilogram, 15 kilogram, 20 kilogram, 25 kilogram, and 30 kilogram Foodgrains	2020-10-24
5	IS 14968:2015	Textiles –High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for packaging 50 kilogram /25 kilogram Sugar	2020-10-24
6	IS 14252:2015	Textiles –High Density Polyethylene (HDPE)/ Polypropylene (PP) Woven Sacks for filling Sand	2020-10-24
7	IS 297:2001	Sodium Sulphide, Technical	2020-12-13
8	IS 4581:1978	Phosphorous Trichloride, pure and Analytical Reagent	2020-12-13
9	IS 11744:1986	Phosphorous Pentachloride, Technical	2020-12-13

Till the end of 2022, out of 63 chemicals under mandatory list, QCO's for 25 chemicals were implemented.

Chemicals under BIS: Mandatory List (Scheme I) (2)

	IS No.	Product	Date of implementation
10	IS 11657:1986	Phosphorous Oxychloride, Technical	2020-12-13
11	IS 3205:1984	Precipitated Barium Carbonate, Technical	2020-12-13
12	IS 4505:2015	Sodium Formaldehyde Sulphoxylate	2020-12-13
13	IS 12928:1990	Precipitated Barium for Ceramic and Glass Industry	2020-12-16
14	IS 11356:2020	Styrene-Butadiene Rubber Latex	2021-10-16
15	IS 7686:2020	3(N, N-DiEthyl) Aminophenol	2021-11-22
16	IS 2012:2006	Red Phosphorus	2021-11-22
17	IS 336:1973	Ether	2021-12-24
18	IS 2080:1980	Stabilized Hydrogen Peroxide	2022-09-22
19	IS 17450:2020	1,3 Phenylenediamine	2022-10-24
20	IS 12124:1987	Rubberseed Fatty Acids	2022-10-24
21	IS 5158: 1987	Specification for Phthalic Anhydride, Technical	2022-12-22
22	IS 14709:1999	n- Butyl Acrylate	2022-12-22
23	IS 5295:1985	Ethylene Glycol	2022-12-22
24	IS 537:2011	Toluene	2022-12-22
25	IS 15030:2001	Terephthalic Acid	2022-12-22

Till the end of 2022, out of 63 chemicals under mandatory list, QCO's for 25 chemicals were implemented.

Chemicals regulated under BIS: Mandatory List (Scheme II)

Chemical Name, Indian Standard No.
Ortho Phosphoric Acid – Specification, IS 798
Polyphosphoric Acid – Specification, IS 17439
Trimethyl Phosphite – Technical Grade, IS 17412

Case Study: BIS Certification for Aniline

Table 1 Requirements for Aniline, Technical
(Clause 3.2)

Sl No.	Characteristic	Requirement	Method of Test, Ref to	
			Annex	Cl No. in IS 5299 : 2001
(1)	(2)	(3)	(4)	(5)
i)	Relative density at 27°C / 27°C	1.018 to 1.019	—	5
ii)	Crystallizing point, <i>Min</i>	-6.4°C	—	8
iii)	Distillation range	5 to 95 ml shall distil within the range of 1°C including 184°C	—	7
iv)	Assay, percent by nitrite value <i>Min</i>	99	A	—
v)	Assay, percent by GC, <i>Min</i>	99.5	B	—
vi)	Nitrobenzene content by GC, ppm <i>Max</i>	50	B	—
vi)	Moisture content, percent by mass, <i>Max</i>	0.3	—	10.2

Case Study: BIS Certification for Aniline

Sr. No.	Tests	clause	IS Reference	Specified requirement given in IS 2833	Observed Value
1	Relative Density	3.2	IS2833	1.018 to 1.019	1.019
2	Crystallization Point Min	3.2	IS2833	-6.4°C	-6.4°C
3	Distillation Range	3.2	IS2833	5 to 95 ml shall distill in the range of 1°C including 184°C	184 to 187°C
4	Nitrite Value Min	3.2 (procedure given in Annex A)	IS2833	99%	99.39%
5	Assay, Percentage by GC Min	3.2 (procedure given in Annex B)	IS2833	100%	99.99%
6	Nitrobenzene Content by GC Min	3.2 (procedure given in Annex B)	IS2833	0%	0.00%
7	Moisture Content Max	3.2	IS2833	0.30	0.29
8	Color	3.1	IS2833	Oily liquid colorless to pale yellow liquid	Oily liquid colorless to pale yellow liquid
9	Odor	3.1	IS2833	Musty Fishy Odor	Musty Fishy Odor

Note: Attach extra sheet, if required

Equipment details: Aniline Case Study

Test Equipment/Chemicals	Identification Numbers	Least Count and Range	Valid Calibration	Tests Used	Clause Reference	Remarks
WEIGHING BALANCE, RELATIVE DENSITY BOTTLE, DISTILLED WATER, FILTER PAPER, THERMOMETER, WEIGH	N-3201012-096 (FOR WEIGHING BALANCE)	e=0.001 g d=0.1mg	CERTIFICATE ATTACHED	Relative Density	Clause 5 of IS 5299	
THERMOMETER, CRYSTALLIZATION TUBE OF OD 25 mm, BEAKER, ICE BATH	-	-	-	Crystallization Point	Clause 8 of IS 5299	-
Distillation apparatus Assembly (Electric Heater, Distillation Flask, Distillation receiver, Thermometer, Condensor, Shelf)	-	-	-	For distillation	Clause 7 of IS 5299	-
APPARATUS: Analytical Balance, Required Glasswares CHEMICALS: Hydrochloric	-	-	-	Assay, percent by	3.2 (Annex A of	-

Manufacturing Machinery Details

Sr No.	Machinery	Make/Identification No.	Production Capacity per day, if applicable	Number	Remarks
1	DM Water Tank	TK-6001	-	TK-6001	-
2	Feed Water Pump	P-6002 A/B/C	-	P-6002 A/B/C	-
3	Condensate Tank	TK-6003	-	TK-6003	-
4	Condensate transfer pump	P-6004	-	P-6004	-
5	Steam recover condenser	E-6005	-	E-6005	-
6	Hydrogen Cooler	E-6100	-	E-6100	-
7	Hydrogen Purge Tank	TK-6101	-	TK-6101	-
8	Hydrogen Suction Tank	TK-6102	-	TK-6102	-
9	Seal Tube	TS-6103	-	TS-6103	-
10	Hydrogen Circulation Blower	B-6104	-	B-6104	-
11	Silencer	SL-6105	-	SL-6105	-
12	Hydrogen Circulation Blower	B-6106	-	B-6106	-
13	Silencer	SL-6107	-	SL-6107	-
14	Hydrogen Feed Back Cooler	E-6108	-	E-6108	-
15	Hydrogen Discharge Tank	TK-6109	-	TK-6109	-
16	Hydrogen Preheater	E-6110	-	E-6110	-
17	NB Preheater-I	E-6111	-	E-6111	-
18	NB Preheater-II	E-6112	-	E-6112	-

Recent updates in late 2022 and future development

- Till the end of 2022, out of 63 chemicals under mandatory list, QCO's for 25 chemicals were implemented. In 2023, QCOs for 38 chemicals will be implemented according to various deadlines.
- Once the chemicals are included in the BIS mandatory list and deadline has passed, after that manufacturers, traders and importers will need BIS certification to be permitted to operate and they must carry the relevant BIS standards specification mark on the packaging and labels of their products.
- Consulting chemicals under various international conventions (e.g. Rotterdam, Stockholm convention) and existing chemical regulations such as MSIHC

Recent updates in late 2022 and future development

- Proposal for new standards: 26
- Standards under wide circulation: 45
- **As per meeting in December 2022, 8 Chemicals were finalized for making them mandatory.**
- **As per the latest update, around 76 new chemical products are under consideration that can be introduced under mandatory certification scheme of BIS.**

1. Ethylene Oxide
2. Monocrotophos
3. Captafol (technical grade)
4. Anhydrous Ammonia
5. Alumina Calcined
6. Sodium Cyanide
7. Toluene Diisocyanate (TDI-80)
8. Industrial Grade Urea (Technical grade Urea)

Take Home Message

- BIS is the National Standard Body for standardization, marking and quality certification of goods.
- BIS registration is required to ensure that only quality products are available for Indian consumers.
- BIS registration is required for every product that is mentioned under the mandatory list of Scheme I and II.
- Most of the chemicals are regulated under Scheme I.
- All documents on the checklist need to be submitted to get the certificate.
- After receiving the BIS certificate, every unit of certified product needs to have a standard mark on them before they reach the Indian market for consumers.
- GPC can provide End to End services for BIS registration of your products. **Contact us at Compliance@in.gpcregulatory.com**

Thank You!

“ *Your Seamless Extension in
Global Regulatory Compliance.* ”



IDEON Science Park, Beta 5.
Scheelevägen 17,
223 63 Lund, Sweden



compliance@gpcregulatory.com



+ 46 (0) 46 211 46 15



www.gpcgateway.com



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