

CDSCO Registration for New Drug Approval: Everything You Should Know

If you are planning to introduce a new drug, medical device, or cosmetic product in India, you must know about CDSCO registration. The Central Drugs Standard Control Organization (CDSCO) is the national authority that gives approval for drugs, medical devices, and cosmetics before they are sold in the Indian market.

In this blog, we will explain everything you need to know about [CDSCO registration online](#), including the process, the documents needed, and how it applies to drugs, medical devices, and cosmetics.

What is CDSCO Registration?

CDSCO works under the Ministry of Health and Family Welfare. It is responsible for regulating the safety, quality, and performance of drugs and other healthcare products in India.

If you are a manufacturer or importer of a new drug, you need CDSCO registration to get permission for selling that product in the Indian market.

Why is CDSCO Registration Important for New Drugs?

New drugs must go through testing and approval before they can be sold. This ensures that the drug is:

Safe for people

Effective for the intended use

Made with high quality standards

Without proper CDSCO approval, it is illegal to sell new drugs in India.

Types of Registrations Under CDSCO

CDSCO offers various types of registrations for different products. These include:

1. Online Drug License

To manufacture or sell a drug, you need an [Online Drug License](#). This license proves that your drug meets the legal and safety standards.

There are two main types of drug licenses:

Retail Drug License – for selling drugs to customers

Wholesale Drug License – for selling drugs in bulk to retailers

2. Medical Device Registration Online

If your product is a medical device, such as a blood pressure monitor, thermometer, or surgical instrument, you must complete [Medical device registration online](#).

Medical devices are divided into four classes:

Class A – Low risk (e.g., thermometers)

Class B – Low to medium risk (e.g., contact lenses)

Class C – Medium to high risk (e.g., infusion pumps)

Class D – High risk (e.g., heart valves)

CDSCO checks whether the device is safe and works properly before giving approval.

3. Cosmetic License Online

If you make or import products like creams, shampoos, or makeup, you need a [Cosmetic License online](#). This ensures that your product follows health and safety rules and does not harm users.

CDSCO Registration Online Process

You can apply for CDSCO approval online through the **Sugam Portal**. This portal makes it easy to submit applications and track your status.

Steps for CDSCO Registration Online:

Create an account on the Sugam portal

Choose the product type (Drug, Medical Device, or Cosmetic)

Fill in the application form

Upload documents like safety data, product information, testing reports, and company certificates

Pay the required fees

Wait for review and approval by CDSCO officers

Documents Required for CDSCO Registration

The documents may vary based on the product type, but generally include:

Application form

Covering letter

Product formula

Label and packaging details

Manufacturing license copy

Test reports

Power of attorney (for importers)

Stability study report

Who Should Apply for CDSCO Registration?

Indian manufacturers of drugs, devices, and cosmetics

Importers who want to bring products into India

Distributors and suppliers

Startups launching new healthcare products

How Long Does the Process Take?

The time for getting CDSCO approval depends on the product type and how complete your documents are. On average, it takes between **30 to 90 days**.

Benefits of CDSCO Registration

Legal permission to sell in India

Builds trust with doctors and customers

Increases brand value

Makes your product eligible for government tenders

Helps in expanding your market

Conclusion

If you're introducing a new drug, medical device, or cosmetic product in India, getting CDSCO registration online is a must. It ensures your product is safe, effective, and legal. Whether it's applying for an Online Drug License, Medical Device Registration Online, or a Cosmetic License Online, following the right process can save you from legal troubles and help your business grow.

Whether it's for a medical device registration online, cosmetic license online, or online drug license, our experts are here to assist you at every stage.

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