

Bringing the power of biologicals to all.

Regenix Biosciences Ltd. · Chennai, India



WHO WE ARE

A single site, from formulation to finished pack.

Regenix manufactures recombinant human insulins, an insulin analogue, a GLP-1 analogue and Enoxaparin Sodium at its own facility at MEPZ-SEZ, Chennai — formulation, aseptic fill-finish, cartridge and pen assembly, quality control and batch release, all in house.

**FORM
28**

CDSCO manufacturing licence

**FORM
28D**

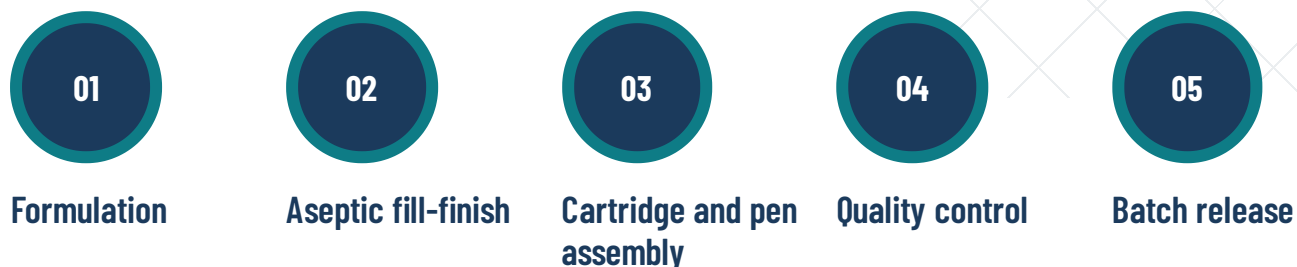
CDSCO licence — Schedule C & C(1)
biologicals

**WHO
GMP**

Certified by CDSCO



How the product is made.



Every step above is carried out at the Chennai site, under one quality system and one batch record.



Formulation



Aseptic fill-finish



Quality control

One quality system

Formulation, filling, assembly, testing and release run under a single quality system, so each batch carries one record from compounding to the finished pack.

Testing on site

Quality control sits alongside production rather than off site, and no batch is released for despatch until its own testing is complete.

Vial to pen in house

Cartridge and pen assembly runs in the same building as filling, so the device is built where the product is made.

Four insulins, a GLP-1 analogue and a heparin.

HUMAN INSULIN, REGULAR / SOLUBLE

Mysulin® R

100 IU/mL · short-acting

10 mL vial, 3 mL cartridge, 3 mL disposable pen



ISOPHANE INSULIN, NPH

Mysulin® N

100 IU/mL · intermediate-acting

10 mL vial, 3 mL cartridge, 3 mL disposable pen



PREMIX INSULIN 30/70

Mixsulin® 30/70

100 IU/mL · biphasic

10 mL vial, 3 mL cartridge, 3 mL disposable pen



INSULIN GLARGINE

SustaGlar®

100 IU/mL · long-acting basal

10 mL vial, 3 mL cartridge, 3 mL disposable pen



LIRAGLUTIDE

Liraslim®

6 mg/mL · GLP-1 analogue

3 mL cartridge with disposable pen



ENOXAPARIN SODIUM

Regeparin®

40 mg and 60 mg · 300 mg

1 mL prefilled syringe; 3 mL cartridge and disposable pen



Four ways to deliver.



10 mL vial

For syringe-based dosing in hospitals and high-volume clinics.



3 mL cartridge

For patients already using a reusable pen device.



3 mL disposable pen

Ready to use, for self-administration outside the clinic.



1 mL prefilled syringe

For Enoxaparin Sodium 40 mg and 60 mg.



WHAT'S IN THE BOX

The product — vial, cartridge or disposable pen — and the pack insert.

Registering across 29 countries.

Regenix products are at various stages of registration across Africa, the Middle East, South and South-East Asia and Latin America, filed through local partners who hold the marketing authorisation in their own market. Registration status differs country by country.



● Registration underway

● Manufacturing site, Chennai

Registration status differs by country and by product.

REGIONS

Africa · Middle East · South and Southeast Asia · Latin America

The partner files

Each registration is filed by a local partner, who holds the marketing authorisation in its own market.

We supply the dossier

CTD dossiers, site documentation and stability data go to the partner, with our regulatory team behind the queries.

One site behind it

Every market is supplied from the same Chennai site, under one quality system.

Three in development.

The following are in development. Nothing on this page is an offer, and availability in any market will depend on completion of development and regulatory approval there.

Insulin Aspart

A rapid-acting insulin analogue.

10 mL vial, 3 mL cartridge,
3 mL disposable pen

Biphasic Insulin Aspart 30/70

A biphasic premix of the rapid-acting analogue.

10 mL vial, 3 mL cartridge,
3 mL disposable pen

Semaglutide

A GLP-1 analogue.

3 mL disposable pen

PLEASE NOTE

These products are not available for supply. They are shown so that partners can plan ahead; no quotation, sample or registration commitment is offered for them, and each will be added to the range only once development and the relevant national approval are complete.

What we can put behind a registration.

CTD dossiers

Prepared in Common Technical Document format.

CoPP, licences and site documentation

On request.

Stability and analytical data packages

Method and stability data to support your filing.

Support through your regulatory queries

Responses drafted with our regulatory team.

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