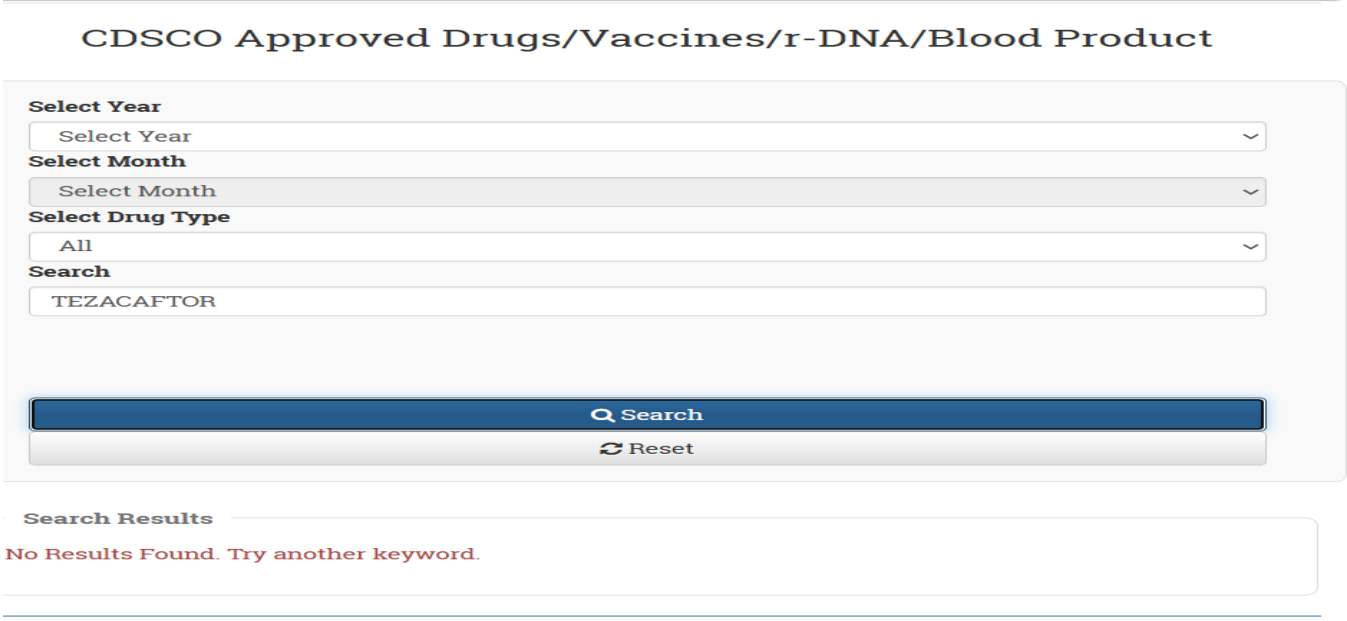
CDSCO Approval & Search Records (Evidence Dossier)

Compilation of official CDSCO SUGAM portal search results and approval entries for Cystic Fibrosis drugs in India.

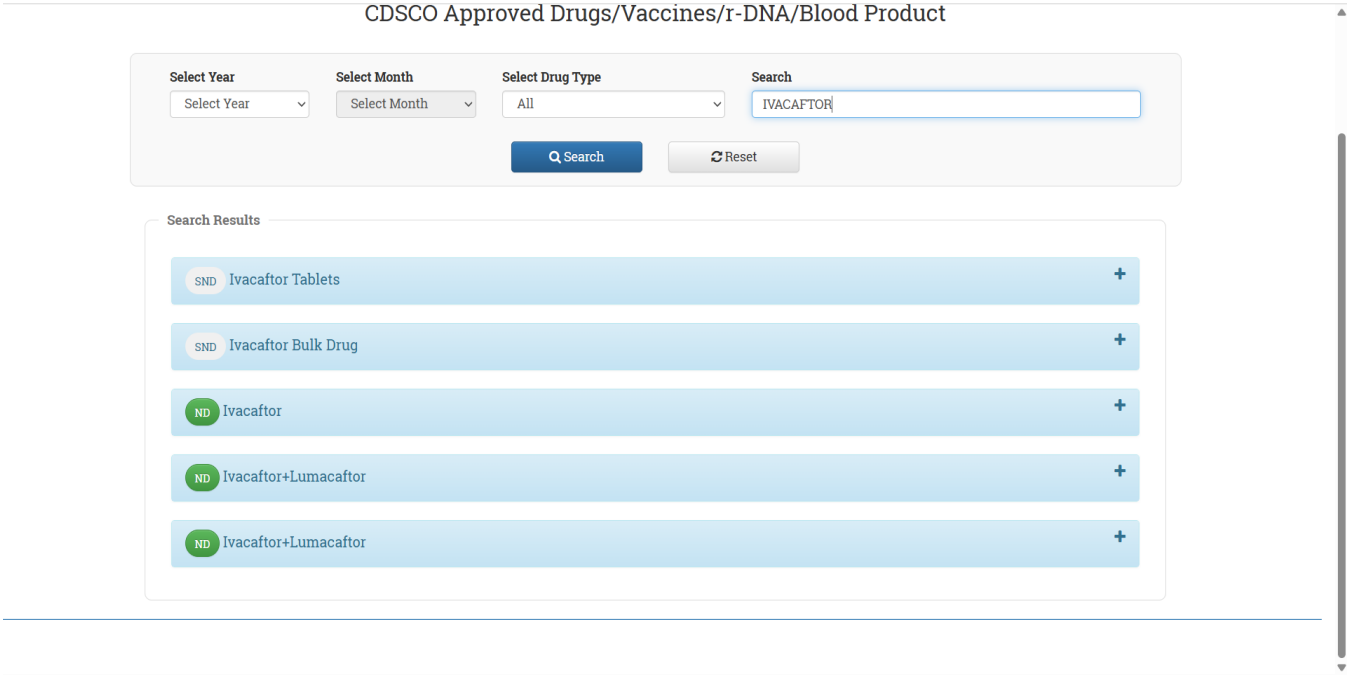
1. Tezacaftor — CDSCO Search (No Results Found)

Official CDSCO SUGAM search confirms zero marketing approvals for Tezacaftor in India.



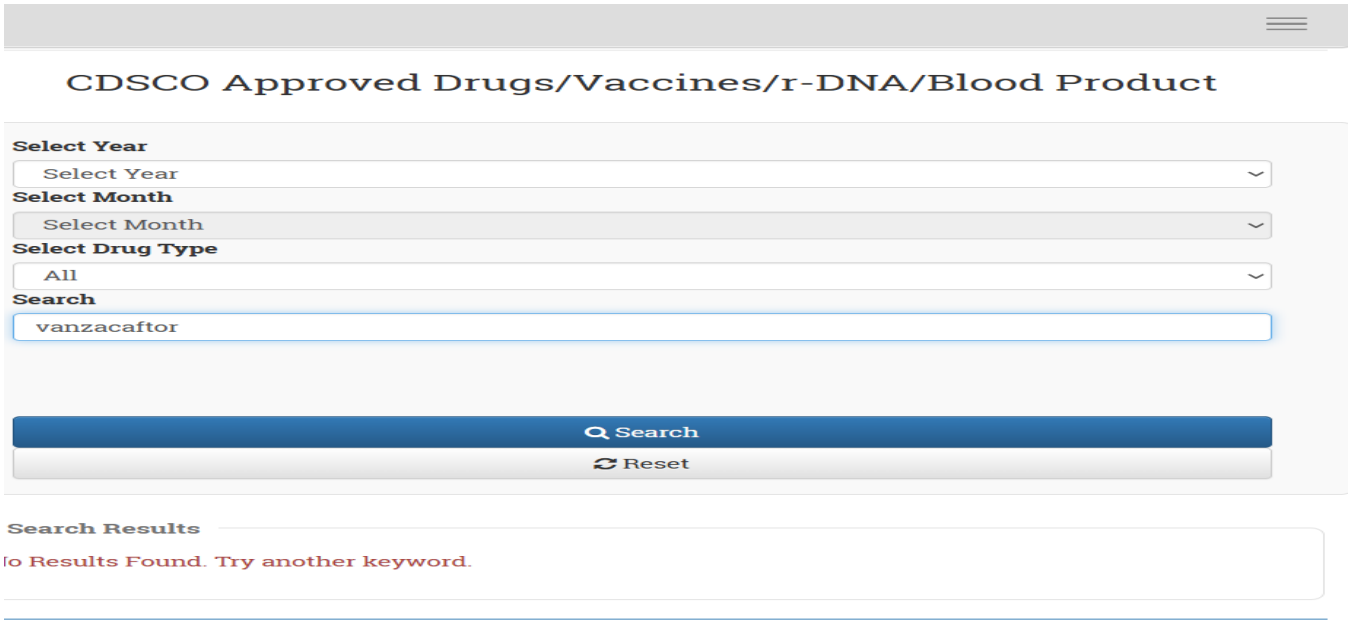
2. Elexacaftor — CDSCO Search (No Results Found)

Official CDSCO SUGAM search confirms zero marketing approvals for Elexacaftor in India.



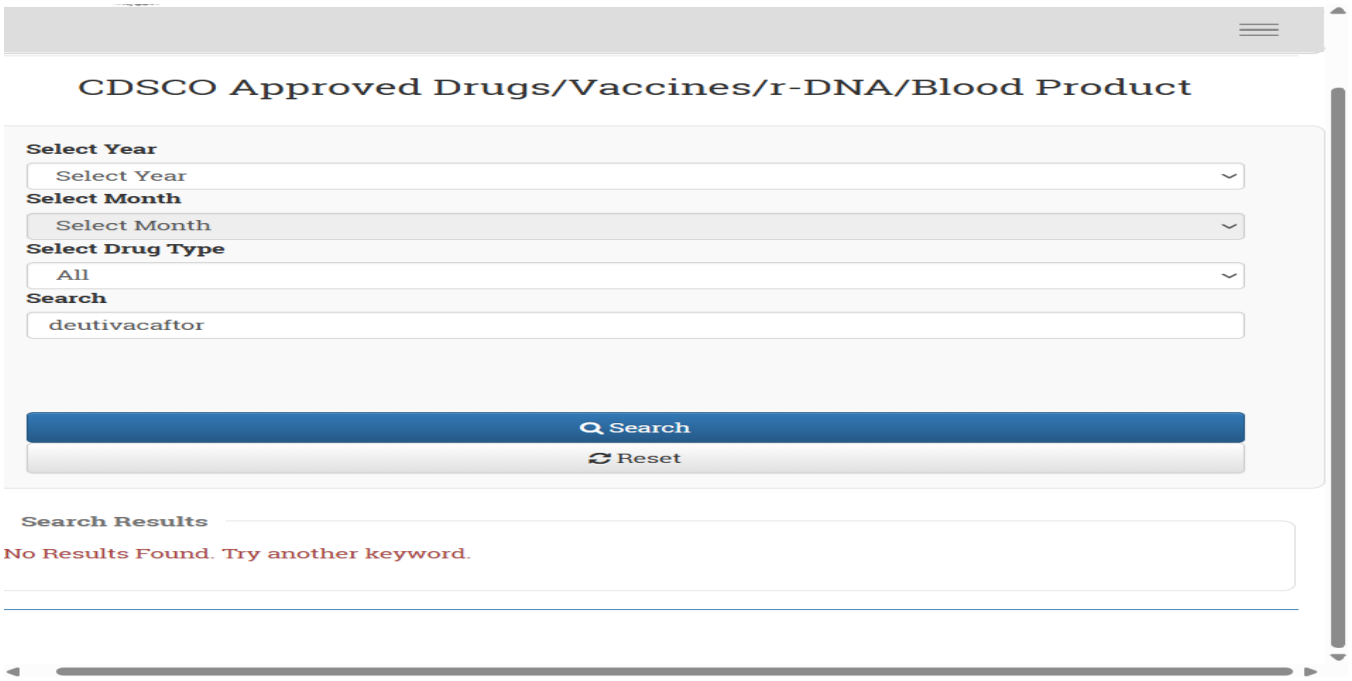
3. Vanzacaftor — CDSCO Search (No Results Found)

Official CDSCO SUGAM search confirms zero marketing approvals for Vanzacaftor in India.



4. Deutivacaftor — CDSCO Search (No Results Found)

Official CDSCO SUGAM search confirms zero marketing approvals for Deutivacaftor in India.



5. Ivacaftor Search Results (Overview)

Master portal search overview displaying all registered Ivacaftor entries in India.

ND Ivacaftor+Lumacaftor

Approval Date :
21-MAR-2022

Type :
Finished Formulation

Composition :
Lumacaftor 100.0000 Milligram (Mg),Ivacaftor 125.0000 Milligram (Mg)

Dosage :
Tablets

Indication :
Cystic Fibrosis (Cf) In Patients Age 2 Years And Older Who Are Homozygous For The F508del Mutation In The Cftr Gene

Manufacturer Name :
LAURUS LABS LIMITED

Manufacturing Site Address :
Laurus Labs Limited, Plot No. Ds1, Ikp Knowledge Park, Turkapally, Shameerpet Mandal , Hyderabad Telangana India-500078

6. MSN Labs — Ivacaftor 150 mg Tablets Approval

CDSCO formulation approval granted to MSN Laboratories Pvt Ltd for Ivacaftor 150 mg.

ND Ivacaftor+Lumacaftor

Approval Date :
21-MAR-2022

Type :
Finished Formulation

Composition :
Lumacaftor 200.0000 Milligram (Mg),Ivacaftor 125.0000 Milligram (Mg)

Dosage :
Tablets

Indication :
Cystic Fibrosis (Cf) In Patients Age 2 Years And Older Who Are Homozygous For The F508del Mutation In The Cftr Gene

Manufacturer Name :
LAURUS LABS LIMITED

Manufacturing Site Address :
Laurus Labs Limited, Plot No. Ds1, Ikp Knowledge Park, Turkapally, Shameerpet Mandal , Hyderabad Telangana India-500078

7. MSN Labs — Ivacaftor Bulk API Approval

CDSCO bulk drug API approval granted to MSN Laboratories Pvt Ltd for Ivacaftor.

ND Lumacaftor

Approval Date :
21-MAR-2022

Type :
Bulk Drug

Dosage :
NA

Indication :
NA

Manufacturer Name :
LAURUS LABS LIMITED

Manufacturing Site Address :
Laurus Labs Limited, Plot No.Ds-1 & 2, Ikp Knowledge Park, Genome Valley, Turkapally Village, Shameerpet Mandal, Medchal District, Hyderabad Telangana India-500078

8. Laurus Labs — Ivacaftor Bulk API Approval

CDSCO bulk drug API approval granted to Laurus Labs Ltd for Ivacaftor.

ND Ivacaftor+Lumacaftor

Approval Date :
21-MAR-2022

Type :
Finished Formulation

Composition :
Lumacaftor 100.0000 Milligram (Mg),Ivacaftor 125.0000 Milligram (Mg)

Dosage :
Tablets

Indication :
Cystic Fibrosis (Cf) In Patients Age 2 Years And Older Who Are Homozygous For The F508del Mutation In The Cftr Gene

Manufacturer Name :
LAURUS LABS LIMITED

Manufacturing Site Address :
Laurus Labs Limited, Plot No. Ds1, Ikp Knowledge Park, Turkapally, Shameerpet Mandal , Hyderabad Telangana India-500078

9. Laurus Labs — Lumacaftor Bulk API Approval

CDSCO bulk drug API approval granted to Laurus Labs Ltd for Lumacaftor.

SND Ivacaftor Tablets

Approval Date :
10-NOV-2026

Type :
Finished Formulation

Composition :
Ivacaftor 150.0000 Milligram (Mg)

Dosage :
Film Coated Tablets

Indication :
Indicated For The Treatment Of Adults, Adolescents, And Children Aged 6 Years And Older And Weighing 25 Kg Or More With Cystic Fibrosis (Cf) Who Have An R117h Cftr Mutation Or One Of The Following Gating (Class Iii) Mutations In The Cystic Fibrosis Transmembrane Conductance Regulator (Cftr) Gene: G551d, G1244e, G1349d, G178r, G551s, S1251n, S1255p, S549n Or S549r

Manufacturer Name :
MSN Laboratories Private Limited

Manufacturing Site Address :
M/S. Msn Laboratories Private Limited, Sy No.317,320,321,322,323,604&605, Rudraram (Village), Patancheru (Manadal), , Sangareddy District Telangana State India-502329
Msn Laboratories Private Limited, Sy No.317,320,321,322,323,604&605, Rudraram (Village), Patancheru(Manadal) , Sangareddy District Telangana State India-502329

10. Laurus Labs — Ivacaftor + Lumacaftor 100mg/125mg Approval

CDSCO approval for Ivacaftor + Lumacaftor combination tablets (100 mg / 125 mg).

SND Ivacaftor Bulk Drug

Approval Date :
25-MAR-2026

Type :
Bulk Drug

Dosage :
NA

Indication :
NA

Manufacturer Name :
MSN Laboratories Private Limited

Manufacturing Site Address :
Msn Laboratories Private Limited., Sy No.317,320,321,322,323,604&605, Rudraram (Village), Patancheru(Manadal), , Sangareddy District Telangana State India-502 329

11. Laurus Labs — Ivacaftor + Lumacaftor 200mg/125mg Approval

CDSCO approval for Ivacaftor + Lumacaftor combination tablets (200 mg / 125 mg).

ND Ivacaftor

Approval Date :
29-MAR-2022

Type :
Bulk Drug

Dosage :
NA

Indication :
NA

Manufacturer Name :
LAURUS LABS LIMITED

Manufacturing Site Address :
Laurus Labs Limited, Plot No.Ds-1 & 2, Ikp Knowledge Park, Genome Valley, Turkapally Village, Shameerpet Mandal, Medchal District, Hyderabad Telangana India-500078