सत्यमेव जयते
Embassy of India
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Carisoprodol in Brazil

1. Executive Summary

Brazil represents a significant market for **Carisoprodol**, particularly as an Active Pharmaceutical Ingredient (API) used in fixed-dose combination medicines. Unlike some markets where carisoprodol is sold primarily as a standalone muscle relaxant, the Brazilian market is dominated by formulations combining **Carisoprodol 125 mg + Diclofenac Sodium 50 mg + Paracetamol 300 mg + Caffeine 30 mg**.

India occupies a strong position in Brazil's import market for carisoprodol. During **January-July 2026, India accounted for approximately 83.8% of Brazil's imports of the product by value**. India's share has remained consistently high in recent years, ranging from approximately 60% to 88% during 2021-2026.

Official pharmaceutical-market data published by Brazil's National Health Surveillance Agency (ANVISA) also indicate a sizeable domestic market for medicines containing carisoprodol. In 2024, the principal fixed-dose combinations containing carisoprodol generated estimated revenues of approximately **R$310-625 million (approximately USD 60-125 million)**, with around **36-85 million packages/boxes** commercialized.

The regulatory environment has, however, become more stringent. Following the inclusion of carisoprodol in **Schedule IV of the 1971 Convention on Psychotropic Substances** in March 2025, ANVISA classified carisoprodol as a **List B1 psychotropic substance** under RDC No. 999/2025. Import quota requirements have applied from **1 March 2026**, making regulatory compliance and coordination with a qualified Brazilian importer particularly important.

Overall, Brazil continues to present a commercially relevant opportunity for Indian manufacturers and exporters of Carisoprodol API, although the market should now be approached with greater attention to ANVISA's controlled-substance requirements.

2. Product and Market Profile

2.1 Principal Use of Carisoprodol in Brazil

The Brazilian market differs from markets where carisoprodol is predominantly marketed as a standalone pharmaceutical product.

A substantial share of Brazilian demand is associated with fixed-dose combination medicines containing approximately:

Carisoprodol 125 mg + Diclofenac Sodium 50 mg + Paracetamol 300 mg + Caffeine 30 mg

These products combine muscle-relaxant, anti-inflammatory and analgesic properties and are well established in the Brazilian pharmaceutical market.

Popular products currently marketed in this category include, inter alia:

- **Tandrilax** - Aché;
- **Torsilax** - Neo Química;
- generic carisoprodol/caffeine/diclofenac sodium/paracetamol formulations marketed by **Eurofarma**; and
- other branded and generic products marketed by Brazilian pharmaceutical companies.

Neo Química describes Torsilax as a combination medicine with muscle-relaxant, anti-inflammatory and analgesic effects, with carisoprodol serving as the muscle-relaxant component. Eurofarma also markets products based on the same combination of active ingredients.

Accordingly, the principal commercial opportunity for overseas suppliers appears to lie in **Carisoprodol API for supply to Brazilian pharmaceutical manufacturers and importers**, rather than in standalone finished-dose carisoprodol products.

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3. Brazil’s Trade in Carisoprodol

3.1 Product Classification

For Brazilian customs purposes, Carisoprodol is classified under:
NCM 29241992 - Carisoprodol

The trade data below relate specifically to Carisoprodol classified under this NCM. Finished pharmaceutical products containing carisoprodol are classified separately and are not included in these figures.

The data have been sourced from **Comex Stat**, the official foreign-trade database maintained by Brazil's Ministry of Development, Industry, Trade and Services (MDIC).
Source: Comex Stat

3.2 Brazil's Imports of Carisoprodol

(FOB USD million)

Year	2026*	2025	2024	2023	2022	2021
Brazil's global imports	3.15	6.37	3.13	8.54	15.56	9.68
Imports from India	2.64	5.62	1.87	6.70	11.81	7.45
India's share (%)	**83.81**	**88.23**	**59.74**	**78.45**	**75.90**	**76.96**

**January-July 2026.*

The recovery to over 88% in 2025 and approximately 84% during January-July 2026 indicates that Indian suppliers continue to enjoy a strong competitive position.

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4. Major Foreign Suppliers

Brazilian imports of Carisoprodol - FOB USD

Country	2026*	2025	2024	2023	2022	2021
India	2,638,364	5,624,318	1,867,580	6,704,398	11,805,513	7,449,388
Italy	504,532	738,542	1,250,110	1,806,713	3,733,210	2,218,377
Germany	1,272	4,231	4,283	12,086	1,532	-
United States	1,116	7,056	3,261	16,795	12,332	12,507
Canada	-	192	-	267	9,311	2,264
France	-	-	-	-	-	573

**January-July 2026.*

The supply structure is highly concentrated. **India and Italy account for virtually the entire commercial import market**, with shipments from other countries being comparatively negligible.

India has consistently maintained a substantial lead over Italy and other suppliers.

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5. Domestic Pharmaceutical Market

Official data from the **2024 Statistical Yearbook of the Pharmaceutical Market**, published by ANVISA's *Câmara de Regulação do Mercado de Medicamentos* (CMED), provide an indication of the size of the Brazilian market for carisoprodol-containing medicines.

5.1 Carisoprodol-Containing Products

Composition	Companies	Products	Packages sold in 2024	Market revenue in 2024
Caffeine anhydrous + carisoprodol + diclofenac sodium + paracetamol	7	7	**25-50 million**	**R$250-500 million**
Caffeine + carisoprodol + diclofenac sodium + paracetamol	5	8	**10-25 million**	**R$50-100 million**
Caffeine + carisoprodol + diclofenac sodium + paracetamol*	2	3	**1-10 million**	**R$10-25 million**
Carisoprodol alone	1	1	**100,000-500,000**	**R$1-10 million**
Carisoprodol + cyanocobalamin + pyridoxine + thiamine	1	1	**Less than 100,000**	**Less than R$100,000**

Sources:
CMED Statistical Yearbook 2024
CMED underlying data

5.2 Market Size Assessment

The data indicate that standalone Carisoprodol represents only a relatively small segment of the Brazilian market.

The commercially important segment is the **fixed-dose combination market**, particularly formulations containing carisoprodol, diclofenac sodium, paracetamol and caffeine.

The principal carisoprodol-containing combinations generated approximately:
R$310-625 million in revenues during 2024, equivalent to roughly **USD 60-125 million**.

The corresponding volume was approximately:
36-85 million packages/boxes sold during 2024.
It should be emphasized that a “package” or “box” does not correspond to a fixed number of tablets. Different registered pharmaceutical presentations contain different quantities of tablets and/or blister strips.

Consequently, CMED’s package-sales data are useful for assessing the **commercial size and depth of the market**, but cannot by themselves be converted into the precise quantity of Carisoprodol API consumed in Brazil.

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6. Regulatory Environment

6.1 International Classification

In March 2025, following a recommendation by the World Health Organization, the **UN Commission on Narcotic Drugs** placed Carisoprodol in:

Schedule IV of the 1971 Convention on Psychotropic Substances.
The decision followed concerns relating to non-medical use and associated public-health risks.

6.2 Classification in Brazil

Following the international scheduling decision, ANVISA issued **RDC No. 999/2025**, adding Carisoprodol to:
List B1 - Psychotropic Substances
under Brazil’s controlled-substances regulatory framework.

Source:
RDC No. 999/2025 - ANVISA

For finished medicines containing carisoprodol, the applicable rule provides for:
sale under medical prescription without retention of the prescription by the pharmacy.

Therefore, the regulatory change does not prohibit the continued prescription or commercialization of carisoprodol-containing medicines in Brazil.

It does, however, subject the substance and its supply chain to substantially greater regulatory oversight.

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7. Import Control Requirements

The regulatory framework for importing Carisoprodol API became significantly more stringent following its classification as a B1 controlled psychotropic substance. Key requirements include:

- classification of Carisoprodol as a **B1 controlled psychotropic substance**;
- application of **ANVISA import quotas from 1 March 2026**;
- prior regulatory authorization for importation by the Brazilian importing entity;
- compliance with ANVISA requirements applicable to controlled substances; and
- appropriate authorization of Brazilian establishments dealing with the substance.

Indian exporters should therefore ensure, before dispatch of any consignment, that the Brazilian importer possesses the necessary regulatory authorization and has access to the requisite import quota.

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8. Port and Airport Restrictions

ANVISA's guidance concerning implementation of **RDC No. 988/2025** provides for restrictions on the ports and airports through which controlled substances covered by the relevant lists may enter or leave Brazil.
Designated locations include:

- **Port of Santos**;
- **Guarulhos International Airport**;
- **Port of Rio de Janeiro**; and
- **Rio de Janeiro International Airport**.

Source:
ANVISA - Questions and Answers concerning RDC No. 988/2025

Exporters should confirm the applicable entry point and import procedure with their Brazilian importer and customs/regulatory representative prior to shipment.

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9. Market Opportunities for Indian Exporters

The Brazilian market presents several favourable characteristics for Indian Carisoprodol suppliers. India already accounts for the majority of Brazil's Carisoprodol imports and therefore enjoys an established position in the supply chain. It may, however, be noted

that Brazil has a sizeable and mature market for carisoprodol-containing combination products, supported by established brands and generic manufacturers.

Continued API Requirement

The large domestic sales volume of fixed-dose combination products implies an ongoing requirement for Carisoprodol API by Brazilian pharmaceutical manufacturers.

Concentrated Supply Base

The Brazilian import market is highly concentrated between India and Italy. This provides Indian manufacturers with an opportunity to consolidate their existing position, particularly where they can offer competitive pricing, quality consistency and assured supply.

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10. Key Challenges and Risks

The following factors should be taken into consideration by prospective Indian exporters:

Regulatory controls: Carisoprodol is now a controlled psychotropic substance in Brazil, making import procedures more complex than for conventional pharmaceutical APIs.

Import quotas: Availability of an ANVISA-approved import quota may determine whether and when an importer can place or execute an order.

Importer capability: Exporters should work with Brazilian importers that possess the necessary experience and authorizations to handle controlled pharmaceutical substances.

Market concentration: While Brazil offers significant demand, the finished-dose market includes well-established domestic pharmaceutical companies and brands.

Import volatility: Brazil's annual import value has fluctuated substantially, from approximately USD 3.1 million in 2024 to USD 15.6 million in 2022. Annual trade values should therefore not be interpreted as a linear indicator of consumption.

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11. Advisory for Indian Exporters

Indian manufacturers/exporters considering the Brazilian market may wish to:

1. **Identify established Brazilian pharmaceutical manufacturers and API importers** supplying carisoprodol-containing fixed-dose combinations.

2. Confirm whether the prospective Brazilian importer possesses the necessary **ANVISA authorizations for controlled substances**.
3. Verify the availability of the requisite **ANVISA import quota before shipment**.
4. Obtain confirmation from the importer regarding the applicable import authorization, port/airport of entry and customs procedures.
5. Monitor amendments issued by **ANVISA** relating to controlled substances, particularly RDC Nos. **988/2025 and 999/2025** and subsequent implementing guidance.
6. Use **MDIC's Comex Stat** for official trade statistics and **ANVISA/CMED** publications for pharmaceutical-market information.

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12. Overall Assessment

Brazil constitutes an established and commercially significant market for Carisoprodol, particularly for use in fixed-dose combination medicines.
India is already the dominant external supplier, accounting for approximately 84% of Brazilian imports during January-July 2026 and maintaining a majority share throughout the period examined.

The Brazilian pharmaceutical market for products containing carisoprodol is substantially larger than the market for carisoprodol as a standalone medicine. Official CMED data point to tens of millions of packages being sold annually and several hundred million reais in market revenues.

The principal change affecting future exports is therefore not a lack of market demand, but the tightening of the regulatory framework. The classification of Carisoprodol as a controlled psychotropic substance has introduced quota, authorization and logistical requirements that exporters and their Brazilian partners must incorporate into their supply arrangements.

Subject to compliance with these requirements, the Brazilian market continues to offer meaningful opportunities for established Indian manufacturers of Carisoprodol API, particularly given India's existing dominant market share and the established demand from Brazil's fixed-dose combination pharmaceutical industry.

Principal Official Sources

Brazilian Trade Statistics:
Ministry of Development, Industry, Trade and Services (MDIC) - Comex Stat
https://comexstat.mdic.gov.br/en/home

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ANVISA - Guidance concerning RDC No. 988/2025
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