

Cortellis Generics Intelligence

What is Manufacturing Status of an API?

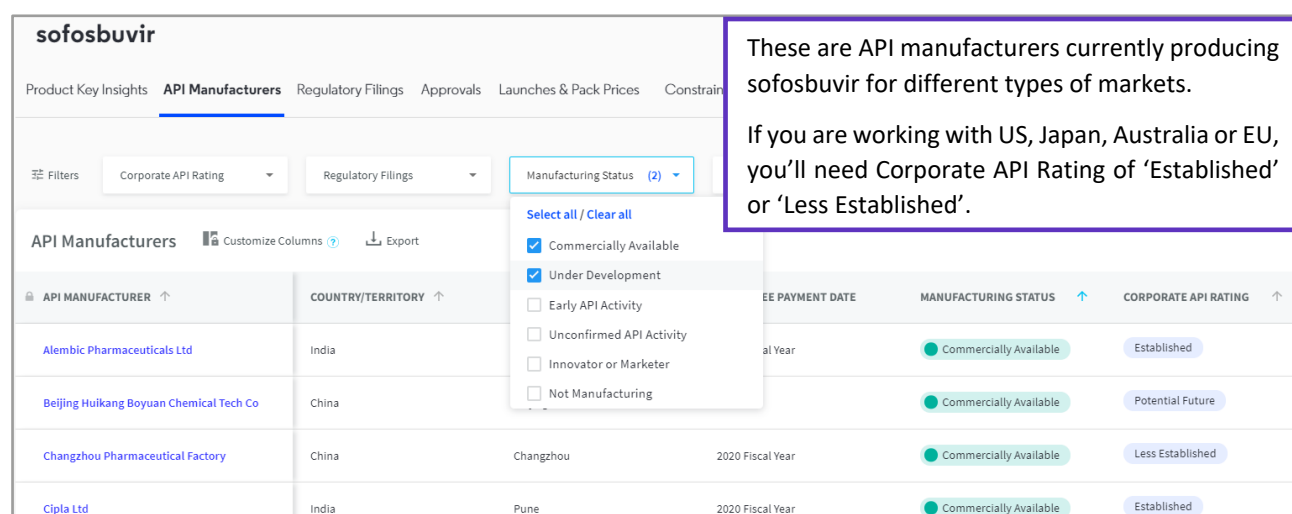
Manufacturing Status is a proprietary analytic to indicate the current manufacturing status, or relationship, between the API and the manufacturing site, according to Cortellis Generics Intelligence. This information is compiled by Cortellis Generics team and validated by experts to help you evaluate suitability of working or competing with this API company.

Manufacturing Status is found in the API Manufacturers tab to indicate the level of production of a product. This can be high (Commercially Available), low (Under Development) or if it needs further research (Early API activity). Here are more details on these definitions:

- **Commercially Available:** Cortellis Generics Intelligence has confirmed with multiple sources that the site is producing or can produce commercial quantities of the API.
- **Under Development:** Cortellis Generics Intelligence has confirmed with multiple sources that the site is developing a process, has the capacity to manufacture clinical trial quantities, or is scaling up production of the API.
- **Early API Activity:** Cortellis Generics Intelligence has learned within the last year that there may be a connection between the API and the manufacturing site but has not yet validated this information with multiple sources.
- **Innovator or Marketer:** API is manufactured by the marketer and/or innovator of the branded product or by a third party for exclusive use by the innovator/marketer.
- **Unconfirmed:** Cortellis Generics Intelligence has not been able to confirm or has conflicting information from multiple sources concerning the status of development at this site.
- **Not Manufacturing:** multiple sources have confirmed that the company is not (and never was) manufacturing this API, has at some time in the past manufactured this API or is trading another company API.

Example:

The selection below was filtered to just those companies manufacturing or developing sofosbuvir. Please note if you are interested in regulated markets - US, Japan, Australia or EU-, you'll need to sort or filter by Corporate API Rating ('Established' and 'Less Established') to display suitable companies.



sofosbuvir

Product Key Insights **API Manufacturers** Regulatory Filings Approvals Launches & Pack Prices Constraints

Filters Corporate API Rating Regulatory Filings Manufacturing Status (2)

API Manufacturers Customize Columns Export

API MANUFACTURER	COUNTRY/TERRITORY	PAYMENT DATE	MANUFACTURING STATUS	CORPORATE API RATING
Alembic Pharmaceuticals Ltd	India		Commercially Available	Established
Beijing Huikang Boyuan Chemical Tech Co	China		Commercially Available	Potential Future
Changzhou Pharmaceutical Factory	China	Changzhou	Commercially Available	Less Established
Cipla Ltd	India	Pune	Commercially Available	Established

These are API manufacturers currently producing sofosbuvir for different types of markets. If you are working with US, Japan, Australia or EU, you'll need Corporate API Rating of 'Established' or 'Less Established'.

Also note that Manufacturing Status depends on the company and the API. This means the same company may have commercial production of sofosbuvir but early development of a different API, for example.

For more information contact Customer Service at [LS Product Support](#)