

Cortellis Generic Intelligence

How do I... find an API Record?

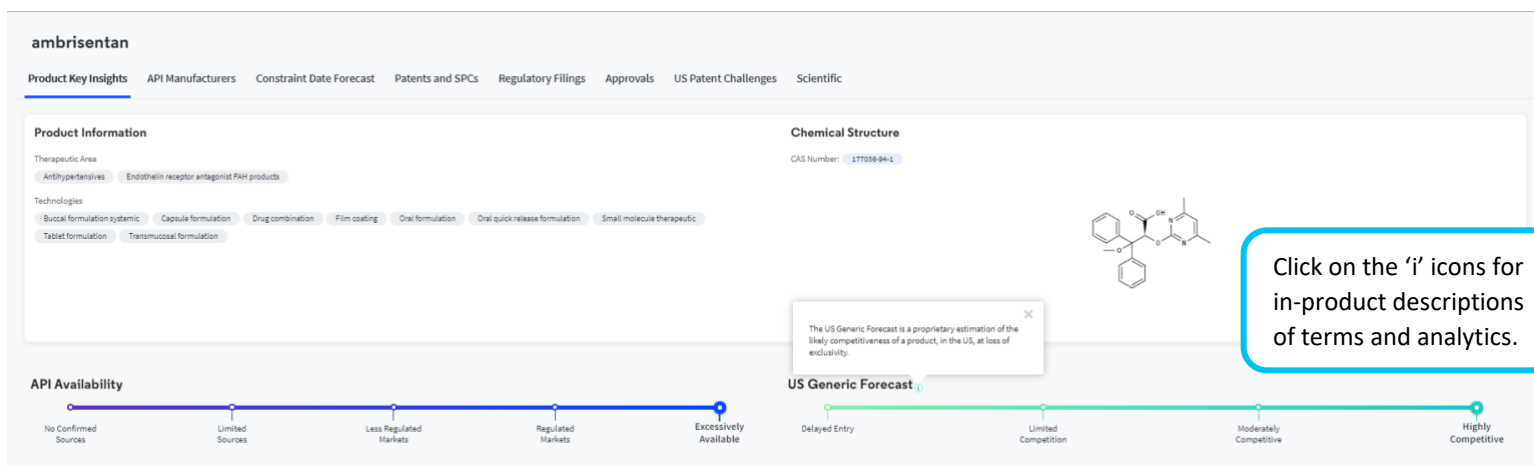
API Records provide a quick assessment of a molecule including key information on manufacturing status, exclusivity and patents including the Constraint Date Forecast*, approval information, dose forms, unique analytics, specifically the API Availability Status and US Generic Forecast, chemical structures and more.

1. Begin by typing the name of your molecule into the search bar and choose from the drop-down list. Icons appear to indicate combination molecules. Select your molecule from the list.



***The Constraint Date Forecast** is the date Cortellis Generics Intelligence predicts a product will lose exclusivity in a market. It's calculated for over 35 markets and it's based on patent and other exclusivity expiries. For more information see the Quick Guide on the Constraint Date Forecast.

2. The Product Key Insights Tab appears providing key information and analytics on the molecule.



Click on the 'i' icons for in-product descriptions of terms and analytics.

Immediately assess how available an API is in the market and how competitive Clarivate believes the US market will be when the molecule goes generic with the above proprietary analytics.

3. Scroll down the page to view a summary of API Intelligence, regulatory filings, patents and more data.

API Manufacturers

Manufacturers by Top Countries

Country	Commercially Available	Under Development	Early API Activity	Innovator or Marketer
India	7	0	0	0
China	3	0	0	0
Malta	1	0	0	0
South Korea	1	0	0	0
Italy	1	0	0	0
All Others	0	0	2	0

Unexpired Constraint Date Forecast and Exclusivities

COUNTRY/TERRITORY	CONSTRAINT DATE	CONSTRAINT DATE RATIONALE
Japan	23-Jul-2020	It is based on the expiry date of the Re-examination Period
France	08-Oct-2020	It is based on the expiry date of an SPC
Ireland	08-Oct-2020	It is based on the expiry date of an SPC
Netherlands	08-Oct-2020	It is based on the expiry date of an SPC

Regulatory Filings (9)

Regulatory Filings by Type

Type	Count	Status
US DMF	8	Active
EU CDS/CEP	0	Valid
KR DMF	1	Registered
JP DMF	0	Registered

Approvals

US Filings and Approvals

Application Type	Count
ANDA	14
NDA	1

Unexpired Patents

Top 5 Patent Territories

Territory	Constraining	Non-Constraining
China	18	0
USA	12	0
Greece	6	0
Spain	5	0
Austria	5	0

Click **View Details** to go to more granular information for each card.

4. Click on the top tabs to view more data.

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Product Key Insights | **API Manufacturers** | Constraint Date Forecast | Patents and SPCs | Regulatory Filings | Approvals | US Patent Challenges | Scientific

Filters: Corporate API Rating | Regulatory Filings | Manufacturing Status | Country/Territory (X)

Filter your results – here we see the results for China.

Customize your display and Export your results

API MANUFACTURER	COUNTRY/TERRITORY	CITY	MANUFACTURING STATUS	CORPORATE API RATING	ACTIVE INGREDIENT	REGULATORY FILINGS	AVAILABLE FOR REF US DMF	ISSUED GMP CERTIFICATES
Tianjin Weijie Pharmaceuticals	China	Tianjin	Commercially Available	Potential Future	ambrisentan	US DMF	No	No
Zhejiang Huahai Pharmaceut	China	Linhai	Commercially Available	Established	ambrisentan	US DMF	Yes	No
Lianyungang Runzhong Phar	China	Lianyungang	Early API Activity	Potential Future	ambrisentan	No data	No	Yes
Lianyungang Guika Pharmac	China	Lianyungang	Unconfirmed API Activity	Potential Future	ambrisentan	No data	No	No
QR Pharmaceuticals Ltd	China	Wuhan	Unconfirmed API Activity	Potential Future	ambrisentan	No data	No	No
Jiangsu Kanion Pharmaceut	China	Lianyungang	Not Manufacturing	Local	ambrisentan	No data	No	No
Sandoz Pharmaceuticals and	China	Ningbo	Not Manufacturing	Local	ambrisentan	No data	No	No
Shanghai SIPi Pharmaceut	China		Not Manufacturing	Potential Future	ambrisentan	No data	No	No
Xiamen Mayah Pharma	China		Not Manufacturing	Local	ambrisentan	No data	No	No
Zhongfu Pharmaceutical Co	China		Not Manufacturing	Potential Future	ambrisentan	No data	No	No

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