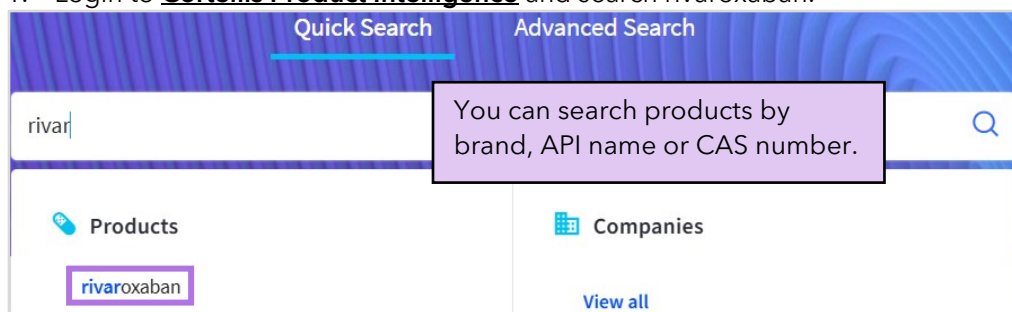


Identify product approvals in different Countries

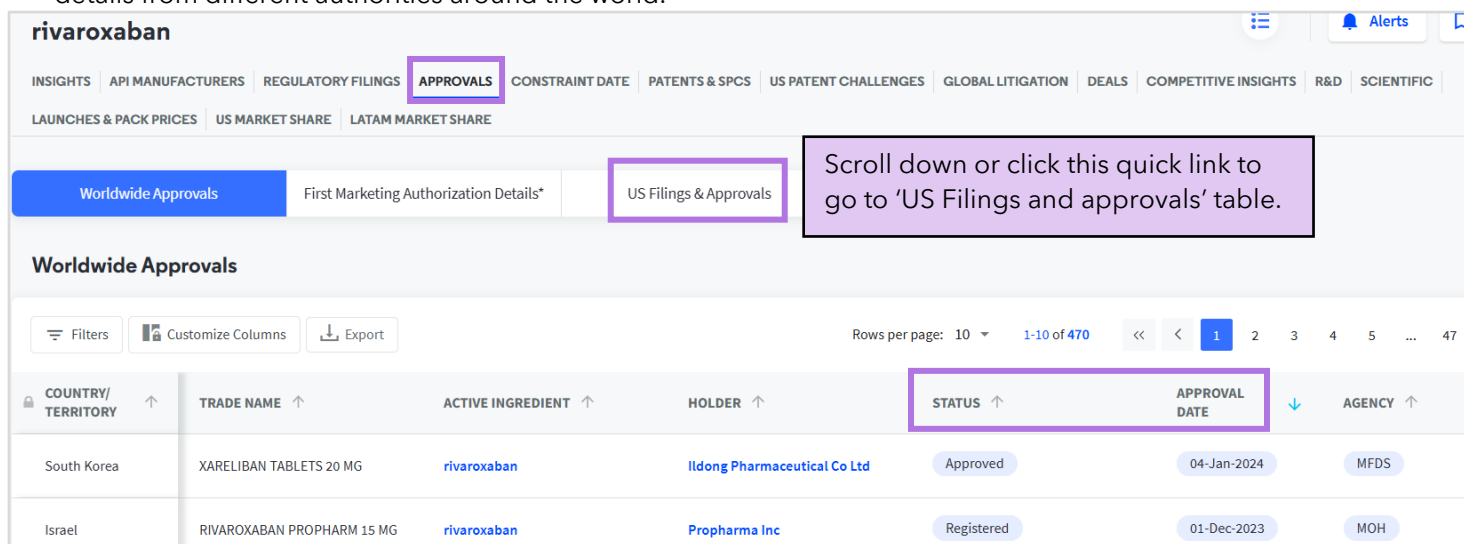
This guide explains how to identify product approvals in different authorities worldwide. The 'Approval' tab in product records helps you understand Marketing Authorization Holders (MAH) and approval dates in different markets as well as the status of NDA, ANDA, BLA and ABLA applications in the US.

Example: Analyze NDA and ANDA filings and approvals of Rivaroxaban in the USA. Which dose forms are included? How many are approved? Is there any dose form/strength with no patent challenges? Who are the filers?

1. Login to **Cortellis Product Intelligence** and search rivaroxaban.



2. Go to 'Approvals' tab. The 'Worldwide Approvals' table displays MAH names, approval dates and other details from different authorities around the world.



COUNTRY/ TERRITORY	TRADE NAME	ACTIVE INGREDIENT	HOLDER	STATUS	APPROVAL DATE	AGENCY
South Korea	XARELIBAN TABLETS 20 MG	rivaroxaban	Ildong Pharmaceutical Co Ltd	Approved	04-Jan-2024	MFDS
Israel	RIVAROXABAN PROPHARM 15 MG	rivaroxaban	Propharma Inc	Registered	01-Dec-2023	MOH

3. Scroll down to 'US Filings & Approvals' table to analyze NDA and ANDA applications, their holders, status, dates and more details, as shown next.

Scroll further to the right to find pediatric extension details when available.

US Filings & Approvals							
Filters		Customize Columns	Export		Rows per page: 10 1-10 of 33		
TRADE NAME	HOLDER	APPROVAL DATE	APPROVAL STATUS	FILING/APPROVAL TYPE	US PATENT CHALLENGES	DOSE FORM	STRENGTH
XARELTO	Johnson & Johnson	20-Dec-2021	Approved - RX	NDA	None reported	For Suspension	1MG/ML
XARELTO	Janssen Pharmaceutica Co Inc	04-Nov-2011	Approved - RX	NDA	PIV	Tablet	15MG
XARELTO	Janssen Pharmaceutica Co Inc	01-Jul-2011	Approved - RX	NDA	PIV	Tablet	10MG
RIVAROXABAN 10MG, 15MG, 2...	Mankind Pharma Pvt Ltd	No data	Filed	ANDA			
RIVAROXABAN 10MG, 15MG, 2...	Cipla Ltd	26-Jan-2024	Tentative	ANDA			

Click 'PIV' to go to US Patent Challenges' tab and read the latest news on each case .

4. Click 'Customize columns' to hide, show and reorder columns in your table.

Filters	Customize Columns	Export
TRADE NAME	Hide All / Show All	
RIVAROXABAN	Trade Name	
RIVAROXABAN	Holder	
RIVAROXABAN	Approval Date	
RIVAROXABAN	Approval Status	
RIVAROXABAN	Filing/Approval Type	
RIVAROXABAN	US Patent Challenges	
RIVAROXABAN	Active Ingredient	

Click 'Export' to download table to MS Excel.

As of Dec 2024:

- The only dose form to not have a PVI certification was suspension of 1mg/ml. All other dose forms did. Twenty-eight ANDAs have been filed from which only 15 are on 'Tentative' status.
- SPCs have been granted in Denmark and Malta. SPCs applications have been filed in 13 other countries in Europe. There are no applications for pediatric extensions.

It is highly recommended to set up email alerts* to monitor updates to this table. These alerts can be set up from the bell icon at the top right of the page.

** Alerts are only available to users with access to Cortellis Product Global and Premium Tier.

* Note: Country coverage includes Brazil ANVISA, EMA, China NMPA, Canada HC, Israel MOH, Italy AIFA, Japan MHLW, Mexico COFEPRIS, Saudi Arabia SFDA, South Korea MFDS and Turkey TITCK.

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