

EXCIPIENT DATABASE

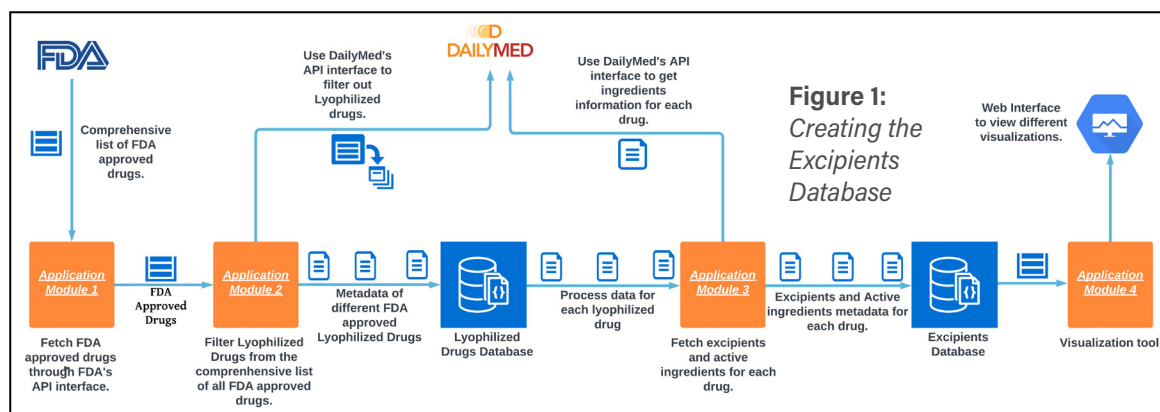
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Excipients are inactive substances that play an important role in the formulation and development of drugs. The study and analysis of excipients used in lyophilized drugs is important as it helps in ensuring the quality and efficacy of such drugs. However, to review the usage of excipients in lyophilized drugs there was a lack of a consolidated resource that documented all inactive ingredients (excipients) used in every FDA-approved lyophilized drug. To address this gap, we created a unique and comprehensive database of all FDA-approved lyophilized drugs from 1954 to 2022. This database

holds information about every FDA-approved lyophilized drug, including the application number filed with the FDA, the date of application filing, the product name, and the company. It also includes information about the active and inactive ingredients used in each drug, including the name and strength of each ingredient used in the drug's formulation.

An application was developed to create this database. The application first gathered a list of more than 23000 FDA approved drugs using FDA's Application Programming Interface (API). This list was then cross-referenced with DailyMed to isolate around 600 lyophilized drugs from the original 23000 drugs. The application stored these lyophilized drugs in a

persistent database. For each of these lyophilized drugs, DailyMed's API endpoints were used to fetch the ingredients information which were then stored in the database. This is represented in **Figure 1**.



The results from the application's database showed that, as of 2022, there have been 622 unique FDA-approved lyophilized drug applications. This number continues to grow each year, with the highest recorded number of applications taking place in 2017, as shown in **Figure 2**.

Furthermore, there is a broad range of excipients utilized in these lyophilized drugs, with over 180 different excipients in use. The most frequently used excipients include mannitol and sodium hydroxide, appearing in over 100 different lyophilized drug formulations, as illustrated in **Figure 3**.

The database not only records the excipients but also the active ingredients used in each drug formulation. The findings indicate that there are approximately 242 different active ingredients utilized among all the lyophilized drugs, with somatropin being the most common, appearing in ten different drug formulations.

