

## USFDA ANNOUNCEMENT REACTION ON INDIAN PHARMA COMPANIES SHARE PRICES- A TEST OF EFFICIENT MARKET HYPOTHESIS THROUGH EVENT STUDY METHODOLOGY

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### **Abstract**

India is one of the important pharma exporters in international pharma market. US is biggest importer of pharma product from India. Most of the Indian companies are listed on Indian Bores. In recent time United States Food & Drugs Administrator audited extensively on Pharma companies. But regulator and investors of security market have raised concerned over the disclosure made by Pharma companies relating to USFDA observation which could impact the investor's wealth.

This study examines the USFDA Announcements and its Reaction on Selected Indian Pharma Companies. The aim of this study is to investigate the extent to which financial markets incorporate information about USFDA Announcements in the pharmaceutical industry. There is dearth of literature about Indian security market and USFDA reaction. The study is aimed at understanding the stock market effect of USFDA announcements which has not been study in the Indian context. This issue is addressed by means of an event study which analyzes the market reaction of 21 Announcements made by USFDA. The study used event study market model. We found that the positive announcement effect was more on the stock price movement and negative announcement impact on stock price movement was less.

**Keyword:** Event Study, Market Model

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## **I. Introduction**

Event study measures the impact of a specific event on the value of a firm. The usefulness of such study comes from the fact that the effect of an event will be reflected immediately in security prices. This measure of the event economic impact can be constructed using stock prices observed over a relatively short time period. In this research paper, our event study is on USFDA (United States Food and Drugs Administration) is responsible for protecting the public health by ensuring the safety, Efficacy, and Security of human and veterinary drugs, biological products and medical devices

FDA Announcements the FDA is responsible for different types of product filings. The two most important filings are New Drug Application (NDA) filings and Biological License Application (BLA) filings. These filings correspond with most innovative products and are of most importance for a company's earning potential and corresponding stock price

Here the USFDA announcement on the particular matter is an event and stock prices are the dependent variables. The event study will investigate the change in stock price of the firm beyond expectation which we call Abnormal Return. The objective of the study is to investigate the effect of USFDA announcement on the particular Pharmaceutical companies stock prices over a period of time called an Event Window. Thus we look at the effect of the announcement 10 days before during and after 10 days of the event on stock prices taking into consideration the daily closing prices of the stocks prior and post announcement.

FDA's goals in India are to obtain information to help make better regulatory decisions about the products from India that are being developed and exported for the U.S. market. This includes medical products being reviewed for marketing authorization in the U.S., and the safety assessment of products that are already on the U.S. market. In addition, the India Office helps verify that foods being imported into the U.S. are safe.

FDA activities in India include:

- Conducting inspections of medical products and foods facilities that export to the U.S.
- Engaging with Indian regulatory authorities to build confidence in each other and

develop quality standards

- Partnering with Indian counterpart agencies on bilateral initiatives
- Assisting and training Indian regulators, Indian pharmaceutical and foods industries, and stakeholders in developing and maintaining the quality, safety, and effectiveness of medical products and foods
- Building and strengthening relationships with the government of India by supporting the mission of the U.S. Embassy.

In this thesis we will study the stock price reaction of companies listed on NSE to USFDA positive and negative announcement made between 2015-2018, stock price movement prior to the announcement will be studied to investigate whether there is systematic stock price anticipation and what its determinants could be, furthermore stock price movement on the announcement date will be studied to identify the determinants of the price shocks.

Lastly, evaluation of stock price on the day following the announcement will be studied to verify whether the response is efficient or not.

## **II. Review of Literature**

- Fama et al (1969) present useful evidence on how stock prices respond to information, Many studies focus on returns in a long run window. While other focus on the short- run window that is few days around the event. A benefit of the short run approach centres around the fact that with daily expected returns being close to zero, the model for expected return tends not have a big effect on inferences about abnormal returns.
- Fama (1970), there exist three forms of market efficiency: weak form- trading on past trend; semi-strong form- trading on publicly available information and past trends; and strong form- trading on any information which may be public or private information.
- Chaney et al (1991), study stock market reaction on new product introduction found that a positive impact of about 0.75% on the stock price during event window of 3-day around the announcement date of new products, but is was found to vary across different industries.
- Brown et al (1993) tends to focus on empirical specification and the power of test statistics in order to detect abnormal stock returns. These studies, therefore, focus on the features of Abnormal return measured on a particular day or at most cumulated over several

months. Similarly, our study looks at the empirical power and specification of test statistics of Abnormal returns on 10days basis of share prices before and after the event for 3years. Thus our work is based on short-run event window of 10days stock returns.

- Peterson P.P(1998) This study provides the review of the state of knowledge and practice with respect to event study methodology. In performing an event study researcher face several options at different points in the process. The paper attempts to provide guidance in the choice of option in doing the event study.
- Blose E L (2003) The paper examines the stock market reaction to USFDA announcement of new drug approval with the event window of 30 days, found that there were no significant positive abnormal returns prior to the announcement of USFDA drug approval, on the other hand, on the day of announcement there were significant positive abnormal returns.
- Malkiel (2003) points out that, no system could be devised to enable abnormal returns to be obtained if one accepts that market equilibrium conditions are translated into expected returns and that these are formed on the basis of the available information. There are equal situations whereby regularities detected in the market, would indicate inefficient information flow leading to a need to formulate a system to enable participants to obtain abnormal gains.
- Simoes et al., (2012) The Efficient Market Hypothesis (EMH) is based on the assumption that, inefficient markets, asset prices fully reflect all available information any change in equilibrium prices will reflect the flow of information available to market participants.
- Schrijver D J(2013) The research focuses on stock responses of NASDAQ and NYSE listed companies of the announcement made by FDA and EMEA both positive and negative announcements. The stock price response of NASDAQ and NYSE listed company's regulatory decision by USFDA and EUROPEAN MEDICINE AGENCY (EMEA). There is a clear difference in stock price response to USFDA and EMEA decision on NASDAQ and NYSE listed companies.
- Flab l.f et al (2017)Examine the reaction of stock returns to acquisition news. A data of 51 observation of acquiring companies with publicly traded shares in London stock exchange is used to analysis with estimation time period of (-100, -10) and the test period of (-5, +5). The market model is applied here in order to predict future stock returns and the use of simple regression to get the parameters of the regression equation with the test statistics obtained

on average is significantly positive and greater than the critical value. Therefore, the event of acquisition does appear to be related significantly to the abnormal returns.

### III. Objective of the study

- To study the impact of USFDA and its impact on stock price movement in India.
- To prove statically that event does affect a company stock price.

### IV. Research Methodology

#### 1. The Event

#### 1. Sun Pharma

Sl. No	Event	Positive Negative News	Impact on stock prices
1	Sun Pharma claims over 3% after USFDA drug approval nod	Positive	On the event day the abnormal return negative
2	Sun Pharma in USFDA cross hair	Negative	On the event day the abnormal return negative
3	Sun Pharma gets observation from USFDA at halol	Negative	On the event day there is positive abnormal return.
4	Sun Pharma climbs 3% after USFDA accepts new drug application	Positive	The abnormal return on the event day is normal.
5	Sun Pharma needs to fix leaking roof contamination risks at halol	Negative	Stock was up on the event day after few days moved down
6.	Completes inspections	Normal reaction	From event day it has proved to be negative for the stock declined

**2. Biocon**

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	USFDA inspection	Normal	On event day the stock price raised up
2	USFDA approval for bio similar drug	Positive	Abnormal return raised before one day of the event day
3	USFDA Approval	Positive	

**3. Glenmark**

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	USFDA gives nod for new drug	Positive	From event day it as started raising

**4. Lupin**

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	Completes inspection	Normal activities	On the event day there is abnormal upside movement
2	Gets Establishment Inspection Report for pithampur facility	Positive	On the event day upside adnormal return
3	Gets approval from USFDA	Positive	Small upside abnormal return on

			the event day
4	USFDA clears goa plant	Positive	Strong upside movement from 9 <sup>th</sup> day onwards
5	Gets approval from USFDA	Positive	Upside movement from 8 <sup>th</sup> day
6	Gets approval from USFDA	Positive	On the event day there is huge spike

### 5. Cipla

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	USFDA for Lopinavir and Ritonavir oral pellets used for treating AIDS in infants and young children	Positive	Normal abnormal returns on the event day

### 6. Cadila Health care

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	USFDA drug nod	Positive	On 8 <sup>th</sup> day the stock as spiked and on the event day it has soared 4%

7. **Dr Reddy**

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	Gets EIR from USFDA for UK plant	Positive	On the huge spike in abnormal returns
2	Gets 4 observations from USFDA for Telangana plant	Negative	On 8,9,10 and 11 <sup>th</sup> day there was upside abnormal return after that there was a dip on event day abnormal return is positive
3	USFDA Inspection	Normal	Abnormal return positive 9,10,11 and 12 + on event day
4	Gets EIR from USFDA for Srikakulam plant	Positive	Huge spike of abnormal return on Event day Positive Movement
5	Dr Reddy's and CHD Bioscience sign up licensing of a wound care drug	Positive	On event day there was small dip and within that day it started increasing
6	Dr Reddy's says new drug approvals will be delayed. The warning letter issued by the USFDA	Negative	Negative on event day



**8. Aurbindo Pharma**

Sl. No	Event	Positive / Negative News	Impact on stock prices
1	Gets USFDA observation	Negative	Negative abnormal return on event day after a small spike on 11 <sup>th</sup> day
2	Gets permission for Fondaparamix Sodium Injection	Positive	Negative abnormal return on the day

**9. Data Sources**

The stock price data has been collected through BSE and Pharma index data are collected through Bloomberg.

**10. The sample**

The sample consist of 8 pharma companies 29 events.

**11. The event window****12. The estimation period****13. Measurement of returns****14. The model**

We have used market model by using Capital Asset Pricing model (CAPM). CAPM calculate the requisite return on security “*i*” in time “*t*” with intercept which is a alpha ( $\alpha$ ) with slope beta ( $\beta$ ) on Parma index in given time “*t*”

$$E(R) = \alpha_i + \beta_i R_{mt} + \epsilon_{it}$$

We have calculated abnormal return by using market adjusted return Brown and Warner (1985), various other literature also used the market model to study announcement effect Zakaria et al (2012) .

The model used in this study is

$$\log_e R_{it} = \alpha_i + \log_e \beta_i R_{mt} + \varepsilon_{it}$$

Where,

$$\frac{P_1}{P_0} \log = \ln \left( \frac{P_1}{P_0} \right)$$

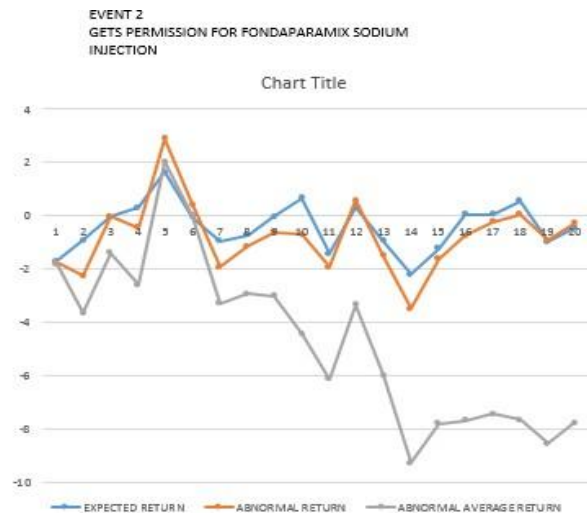
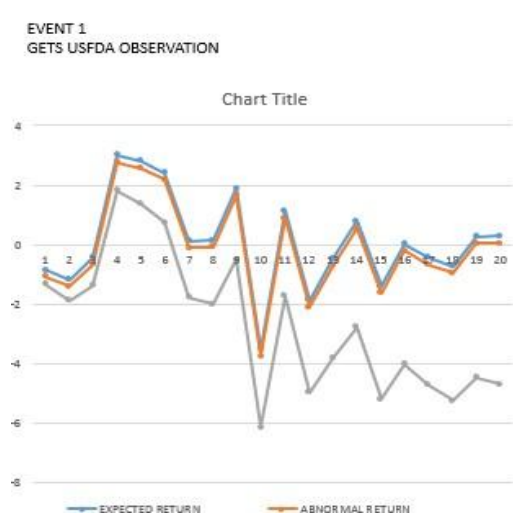
$P_0$

Natural log of continuous compounding rate of return with  $P_1$  is current daily closing price and  $P_0$  is daily previous closing prices,

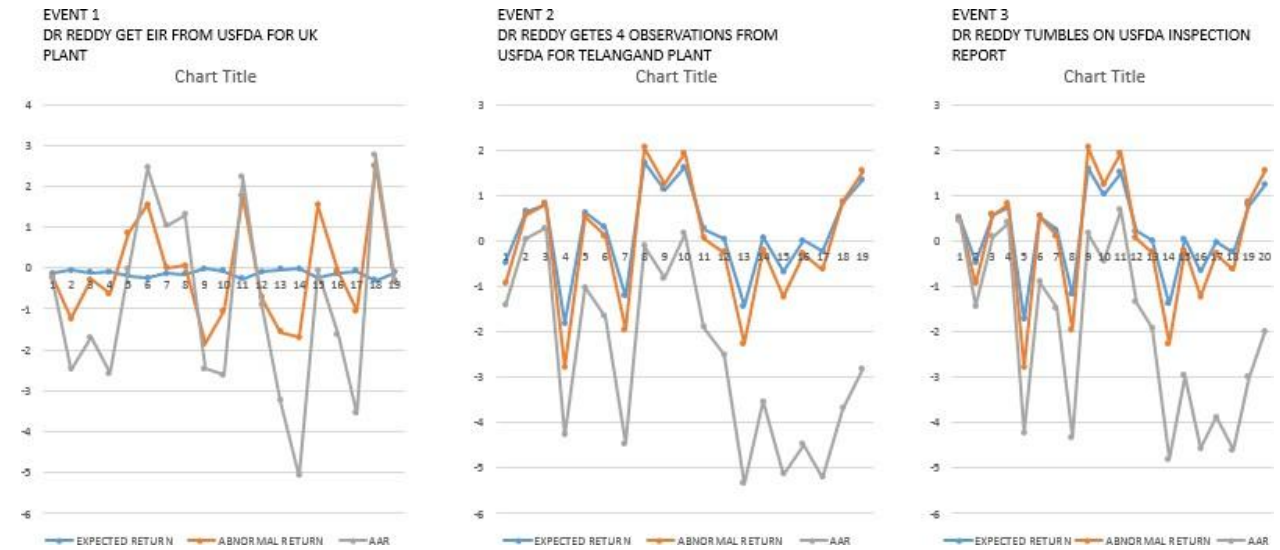
**15. Statistical test for significance**

**V. Empirical findings**

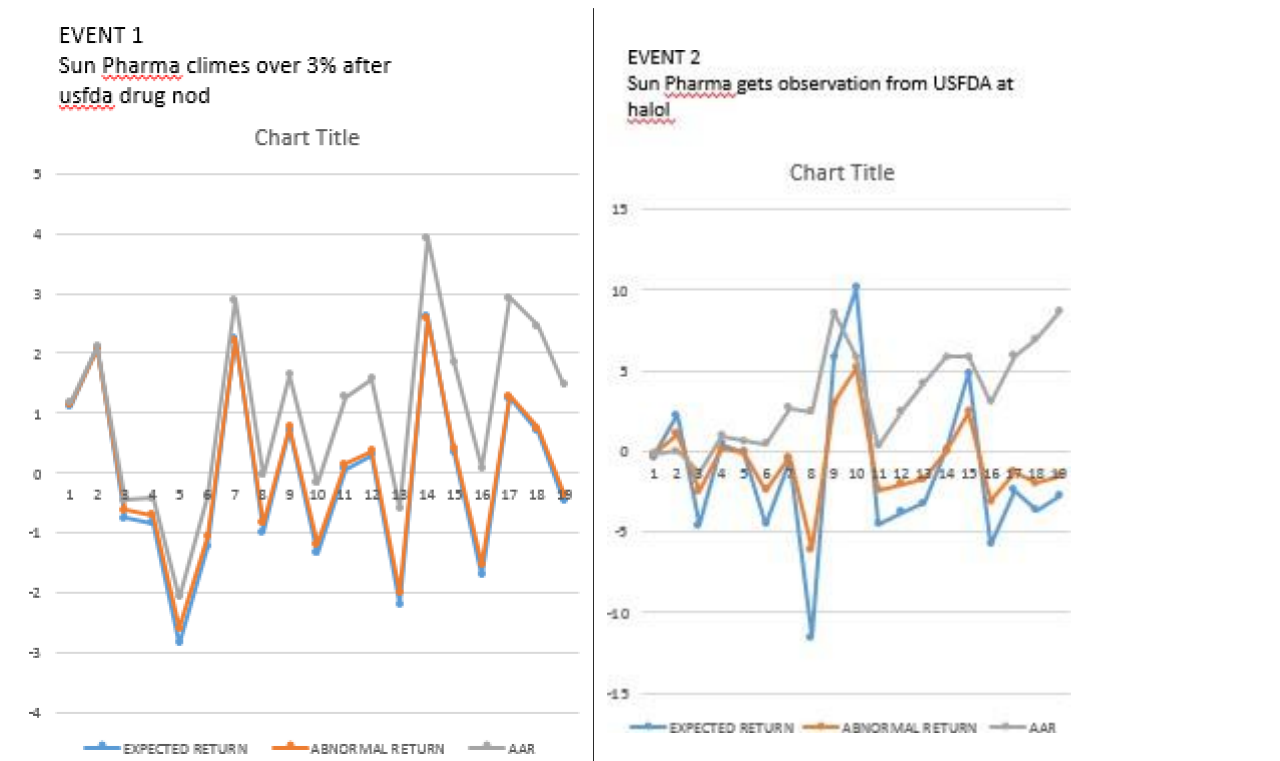
**AURBINDO PHARMA**



## DR REDDY



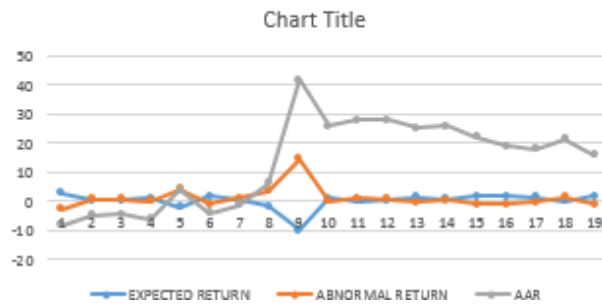
## SUNPHARMA



## BIOCON

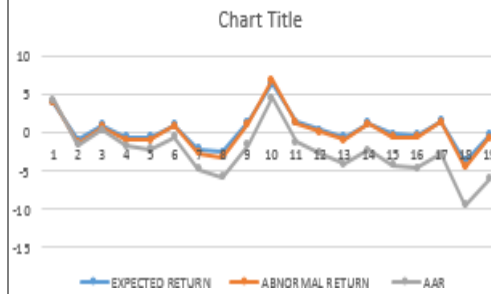
### EVENT 1

BIOCON gets USFDA approval to biosimilar drug



### EVENT 2

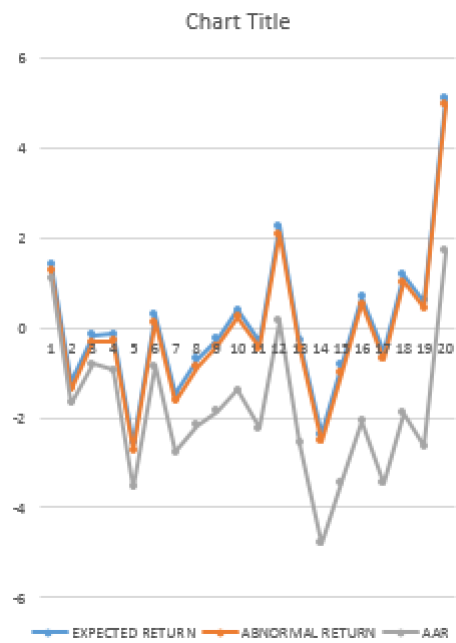
BIOCON IN USFDA INSPECTION, STOCK SLIPS 2%



## LUPIN

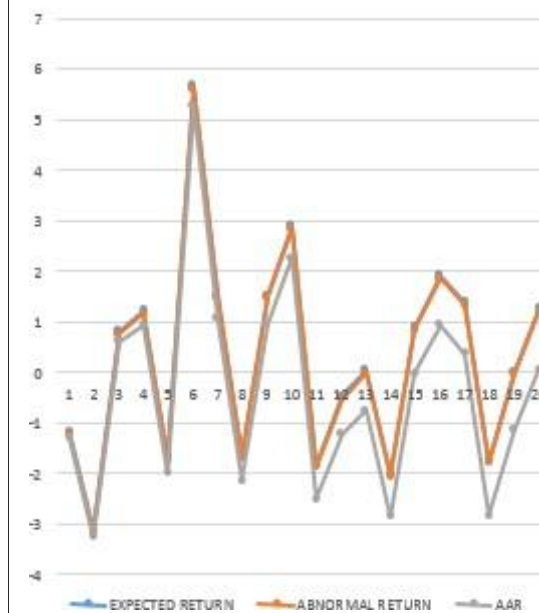
### EVENT 1

Completes Inspection



### EVENT 2

Gets EIR for Pithampur facility



## Limitation

1. The study is limited to only 3 years data .i.e. from 01-01-2015 to 24-05-2018.
2. The study focuses on only few research methodologies which may not give a perfect analysis.
3. Only secondary data is considered.
4. The event study considers only USFDA announcements as an event. There might be other news or factors affecting the price which is not taken into account.

### **Conclusion**

1. Through our analysis we can interpret that positive announcement effect was more on the stock price movement and negative announcement impact on stock price movement was less.
2. Through our event study we lastly conclude that yes USFDA event's does affect Indian Pharma company's stock price whether it is a positive news or a negative news.

### **Reference**

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