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## 10.1 Annexure-1

### Drugs (Prices Control) Order 1995

The Gazette of India - Extraordinary  
PART II - Section 3 - Sub-Section (ii)  
Ministry of Chemicals and Fertilizers  
Department of Chemicals and Petrochemicals  
New Delhi, dated the 6th January, 1995

#### ORDER

S.O. 18 (E). : In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order, namely:-

#### 1. Short title and commencement :

- This Order may be called the Drugs (Prices Control) Order, 1995.
- It shall come into force on the date of its publication in the Official Gazette.

#### 2. Definitions : In this Order, unless the context otherwise requires, -

- "**bulk drug**" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation;
- "**capital employed**" means net fixed assets plus working capital of a manufacturer in relation to manufacture of bulk drugs;
- "**ceiling price**" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of paragraph 9;
- "**dealer**" means a person on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes his agent;
- "**distributor**" means a distributor of drugs or his agent or a stockist appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer;
- "**drug**" Includes -
  - all medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis treatment, mitigation, or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
  - such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by notification in the official Gazette; and
  - bulk drugs and formulations;
- "**Form**" means a form specified in the Second Schedule;
- "**formulation**" means a medicine processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include -
  - any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.

- any medicine included in the Homeopathic system of medicine; and
  - any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;
- "**free reserve**" means a reserve created by appropriation of profits, but does not include reserves provided for contingent disputed claims, goodwill, revaluation and other similar reserves;
- "**Government**" means the Central Government;
- "**import**" with its grammatical variations and cognate expressions means bringing into India from a place outside India, and "importer", in relation to any goods at any time between their importation and consumption, includes any owner or any person holding himself out to be the importer;
- "**manufacture**" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly;
- "**manufacturer**" means any person who manufactures a drug;
- "**net-worth**" means the paid-up share capital of a company plus free reserve, if any, and surpluses excluding outside investments which are not readily available for operational activity;
- "**non-Scheduled bulk drug**" means a bulk drug not specified in the First Schedule;
- "**non-Scheduled formulation**" means a formulation not containing any bulk drug specified in the First Schedule;
- "**pre-tax return**" means profits before payment of Income-tax and surtax and includes such other expenses as do not form part of the cost of formulation;
- "**price list**" means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list;
- "**retail price**" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price;
- "**retailer**" means a dealer carrying on the retail business of sale of drugs to customers;
- "**Scheduled bulk drug**" means a bulk drug specified in the First Schedule;
- "**Scheduled formulation**" means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs, including one or more than one drug or drugs not specified in the First Schedule except single ingredient formulation based on bulk drugs specified in the First Schedule and sold under the generic name;
- "**sale turn-over**" means the product of units of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied retail price inclusive of sales tax, if any, paid or direct sales by the manufacturer or importer but does not include excise duty and local taxes, if any;
- "**Schedule**" means a Schedule annexed to this Order;
- "**wholesaler**" means a dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or research institution purchasing bulk quantities of drugs

## 10.2 Annexure-2

### The First Schedule

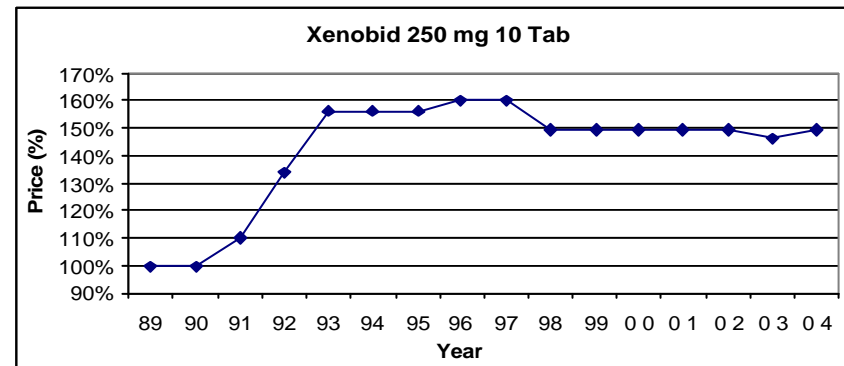
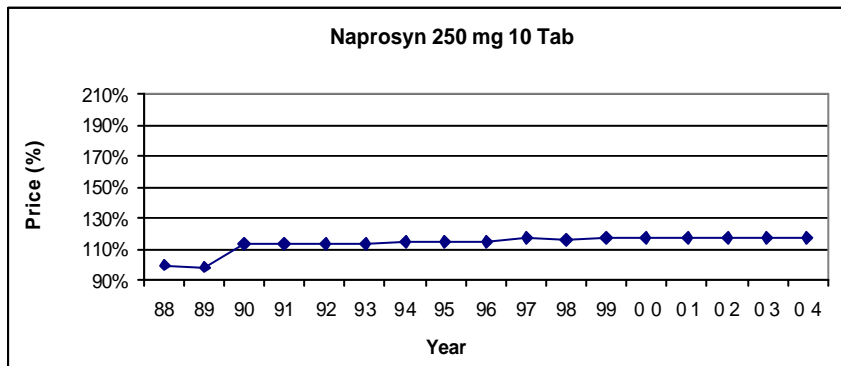
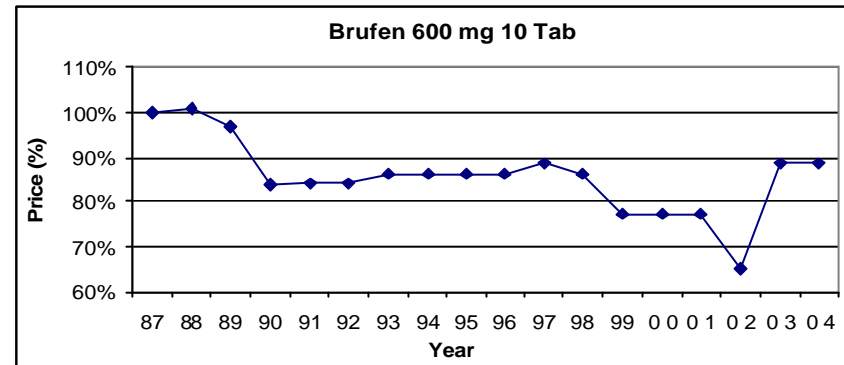
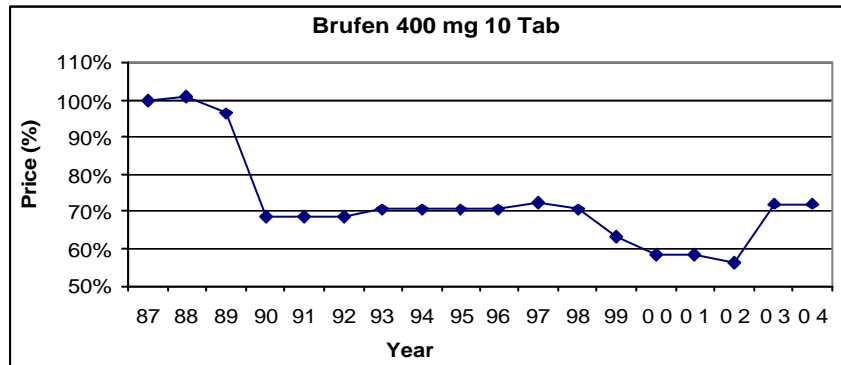
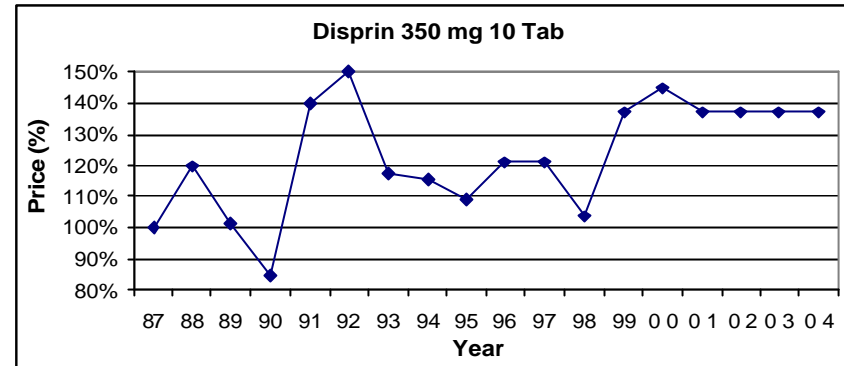
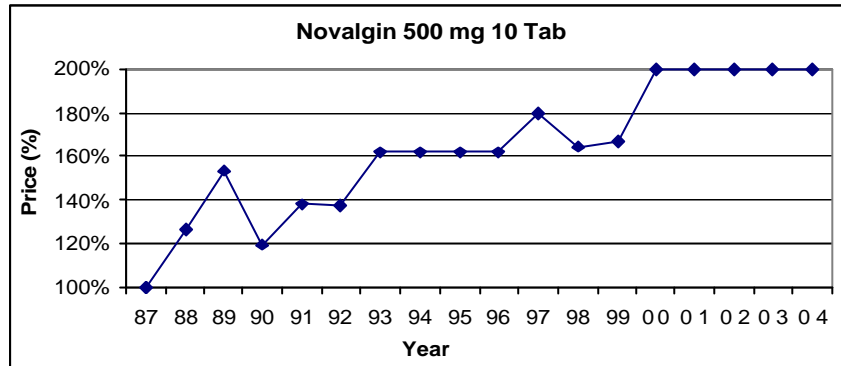
List of Price Controlled Drugs (DPCO 1995)

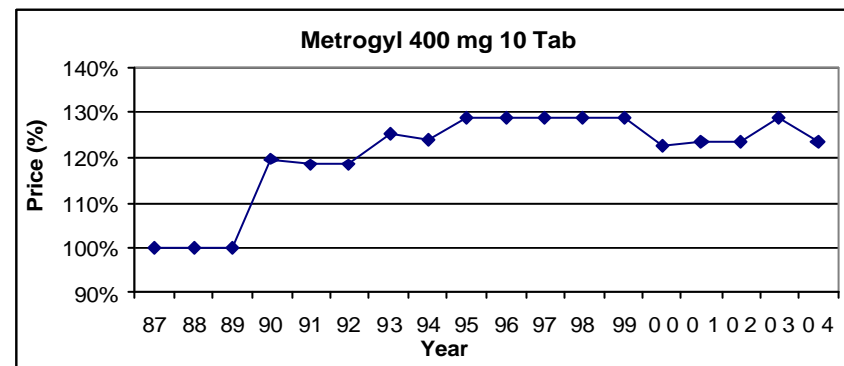
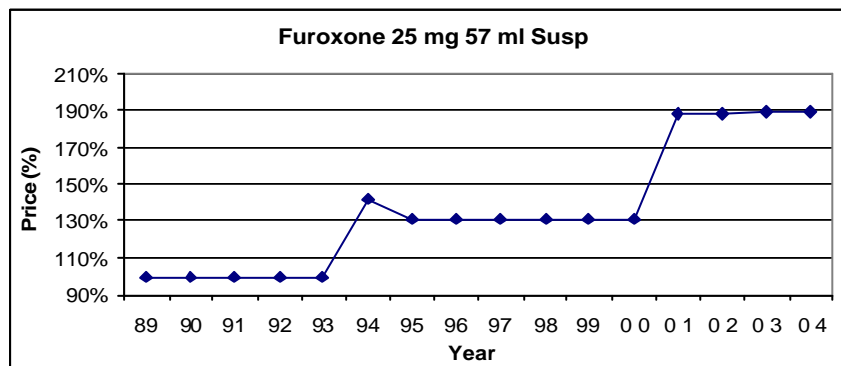
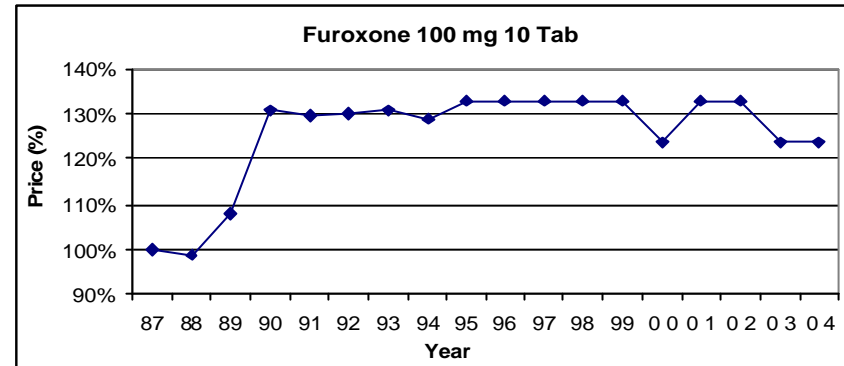
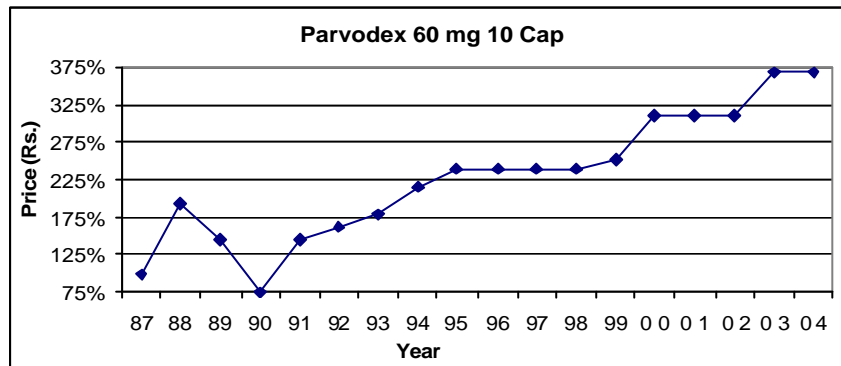
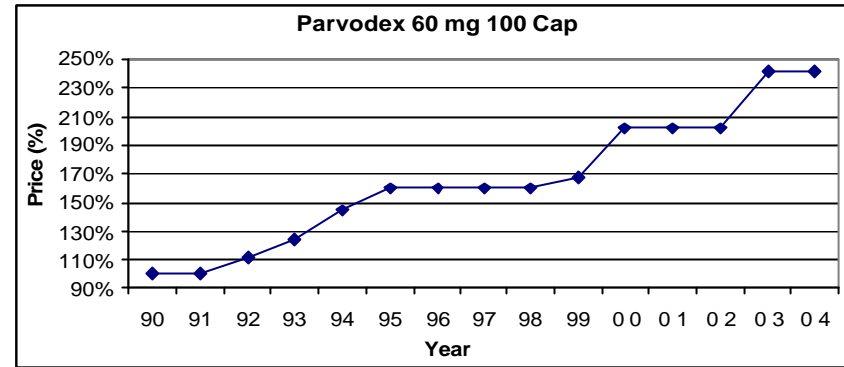
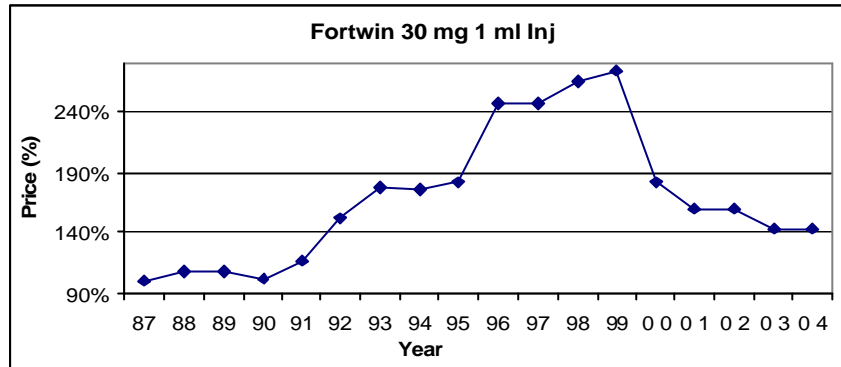
#### BULK DRUGS

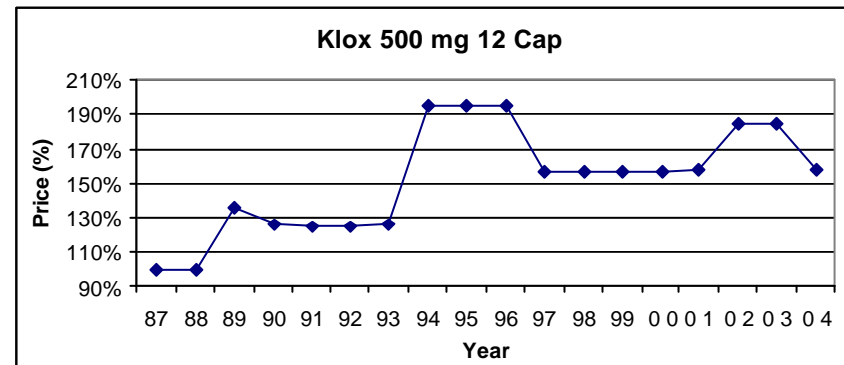
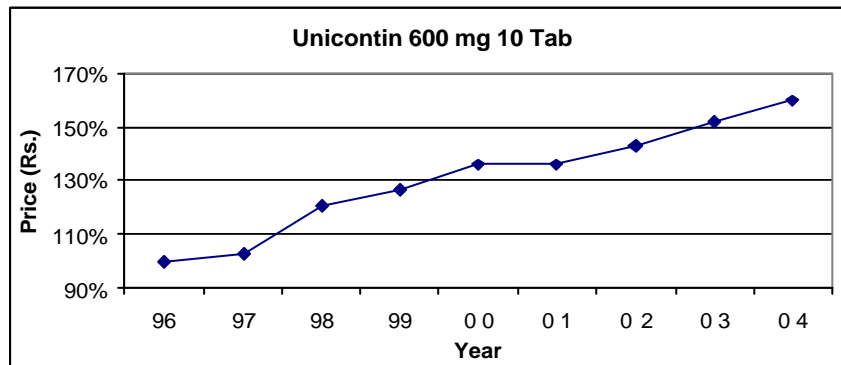
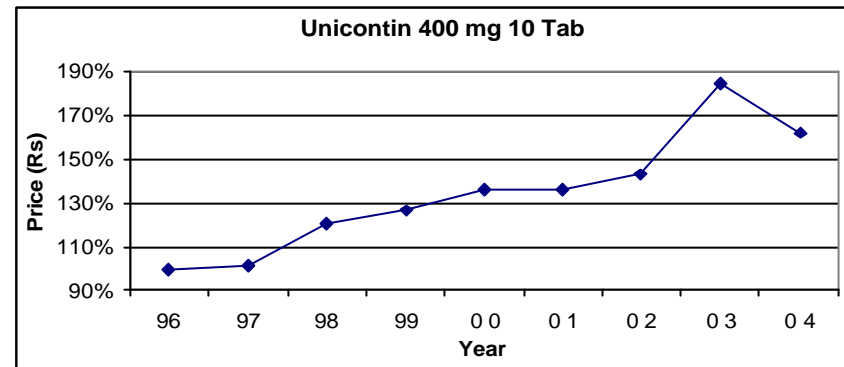
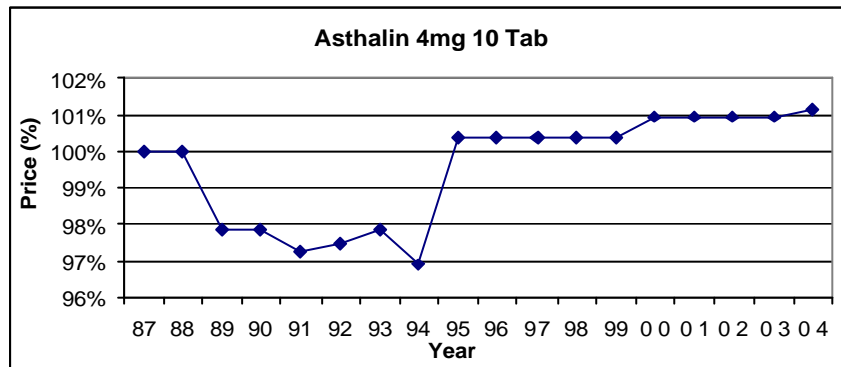
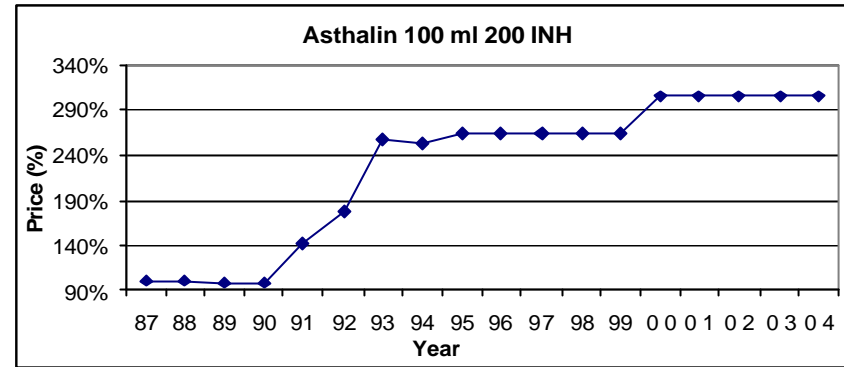
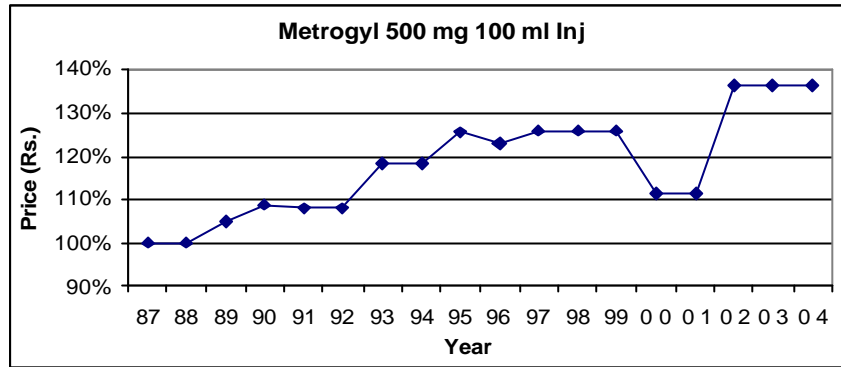
- |                             |                                  |
|-----------------------------|----------------------------------|
| 1. SULPHAMETHOXAZOLE        | 39. GRISEOFULVIN                 |
| 2. PENICILLINS              | 40. GENTAMICIN                   |
| 3. TETRACYCLINE             | 41. DEXTROPROPOXYPHENE           |
| 4. RIFAMPICIN               | 42. HALOGENATED HYDROXYQUINOLINE |
| 5. STREPTOMYCIN             | 43. PENTAZOCINE                  |
| 6. RANITIDINE               | 44. CAPTOPRIL                    |
| 7. VITAMIN C                | 45. NAPROXEN                     |
| 8. BETAMETHASONE            | 46. PYRENTAL                     |
| 9. METRONIDAZOLE            | 47. SULPHADOXINE                 |
| 10. CHLOROQUINE             | 48. NORFLOXACIN                  |
| 11. INSULIN                 | 49. CEFADROXYL                   |
| 12. ERYTHROMYCIN            | 50. PANTHONATES & PANTHENOLS     |
| 13. VITAMIN A               | 51. FURAZOLIDONE                 |
| 14. OXYTETRACYCLINE         | 52. PYRITHIOXINE                 |
| 15. PREDNISOLONE            | 53. SULPHADIAZINE                |
| 16. CEPHAZOLIN              | 54. FRAMYCETIN                   |
| 17. METHYLDOPA              | 55. VERAPAMIL                    |
| 18. ASPIRIN                 | 56. AMIKACIN SULPHATE *          |
| 19. TRIMETHOPRIM            | 57. GLIPIZIDE                    |
| 20. CLOXACILLIN             | 58. SPIRONOLACTONE               |
| 21. SULPHADIMIDINE          | 59. PENTOXYFYLLINE               |
| 22. SALBUTAMOL              | 60. AMODIAQUIN                   |
| 23. FAMOTIDINE              | 61. SULPHAMOXYLE                 |
| 24. IBUPROFEN               | 62. FRUSEMIDE                    |
| 25. METAMIZOL (ANALGIN)     | 63. PHENIRAMINE MALEATE          |
| 26. DOXYCYCLINE             | 64. CHLOROXYLENOLS               |
| 27. CIPROFLOXACIN           | 65. BECAMPICILLIN                |
| 28. CEFOTAXIME              | 66. LINCOMYCIN                   |
| 29. DEXAMETHASONE           | 67. CHLORPROPAMIDE               |
| 30. EPHEDRINE               | 68. MEBHYDROLINE                 |
| 31. VITAMIN B1 (THIAMINE)   | 69. CHLORPROMAZINE               |
| 32. CARBAMAZEPINE           | 70. METHENDIENONE                |
| 33. VITAMIN B2 (RIBOFLAVIN) | 71. PHENYL BUTAZONE              |
| 34. THEOPHYLLINE            | 72. LYNESTRANOL                  |
| 35. LEVODOPA                | 73. SALAZOSULPHAPYRINE           |
| 36. TOLNAFTATE              | 74. DIOSMINE                     |
| 37. VITAMIN E               | 75. TRIMIPRAMINE                 |
| 38. NALIDIXIC ACID          | 76. MEFENAMIC ACID *             |

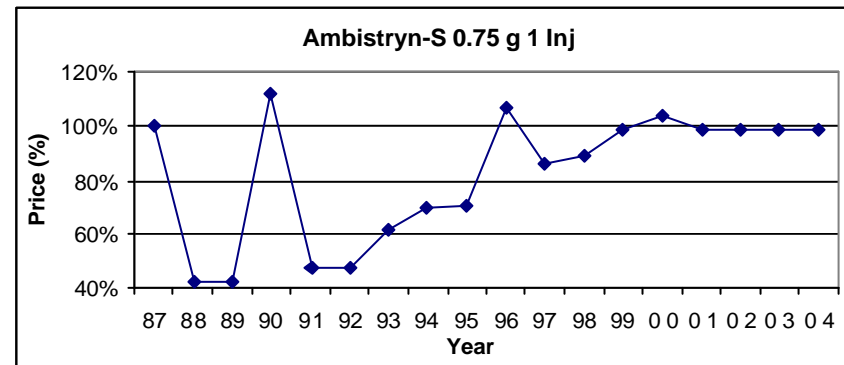
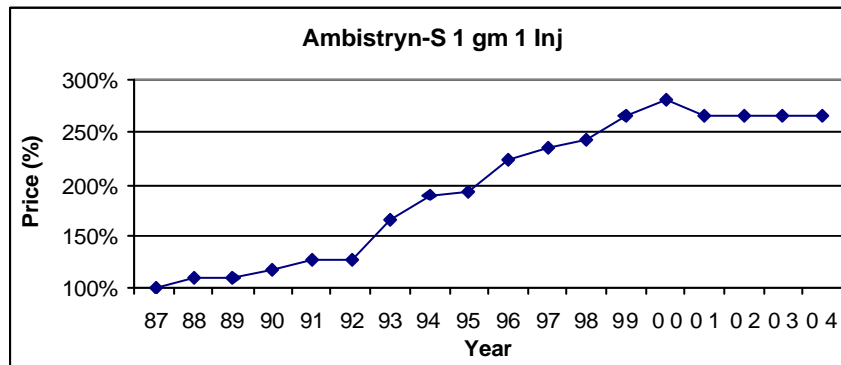
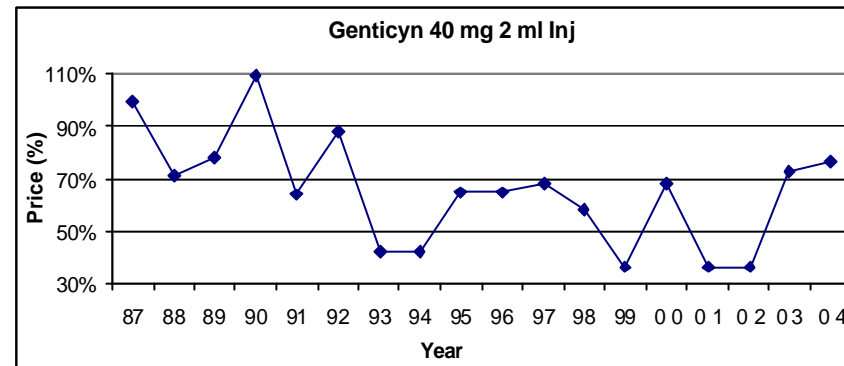
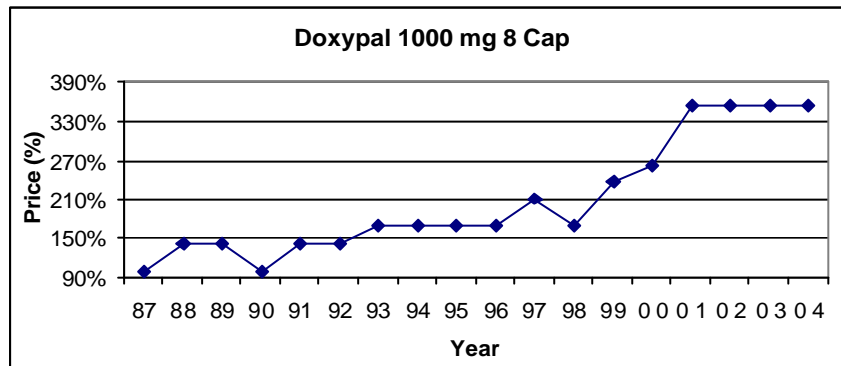
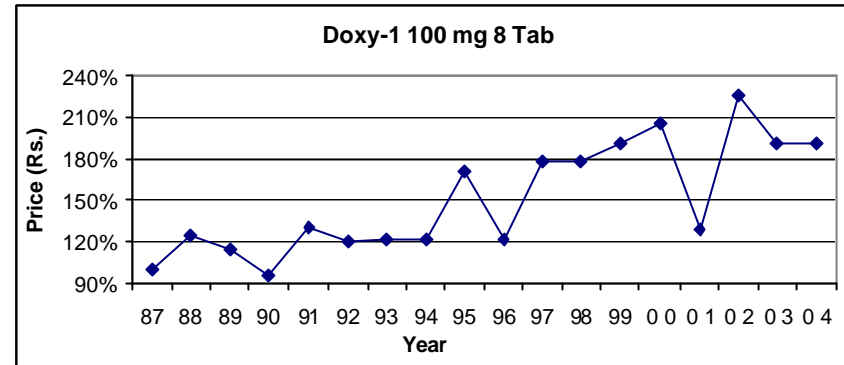
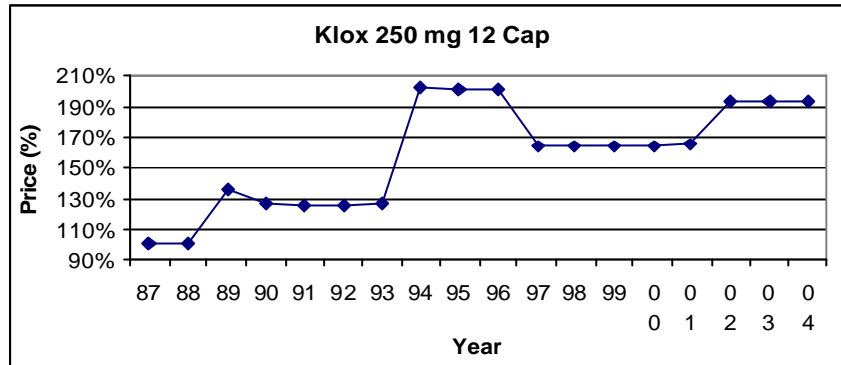
\*Amikacin Sulphate and Mefenamic Acid were omitted by S.O. 626(E) dated 2/9/1997

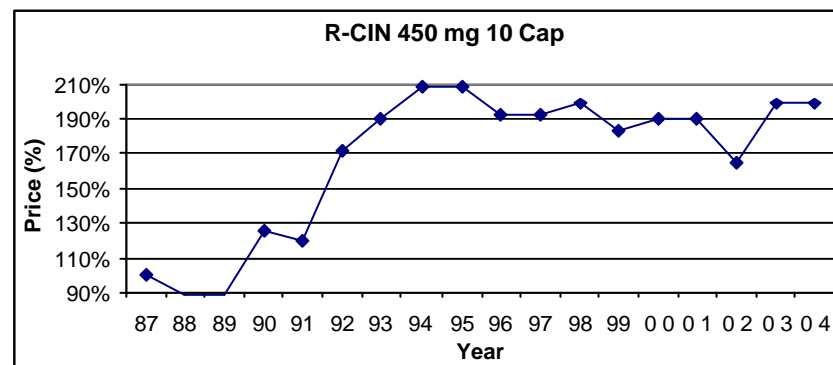
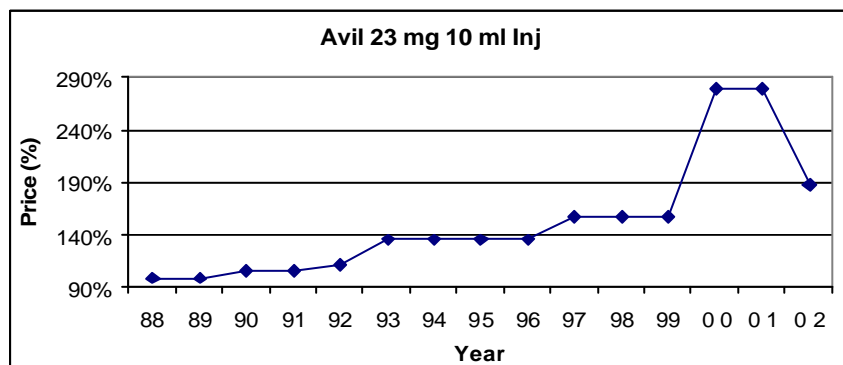
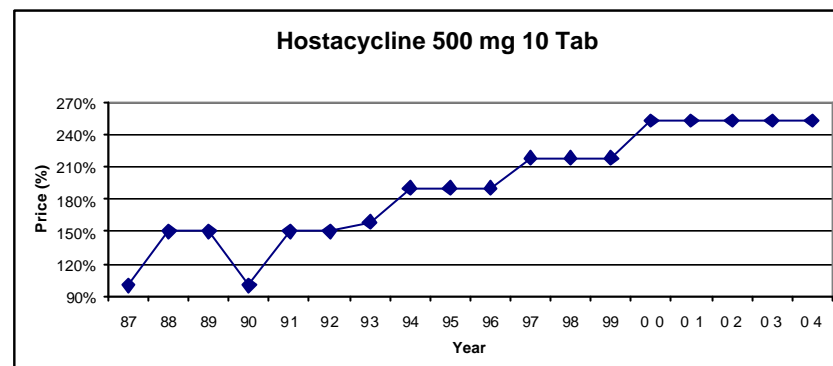
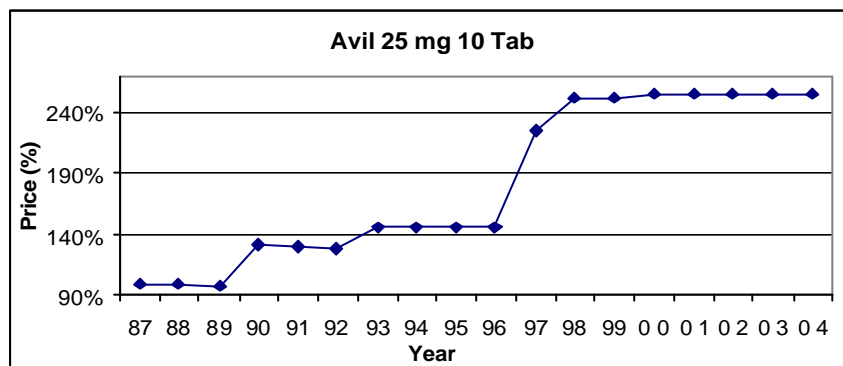
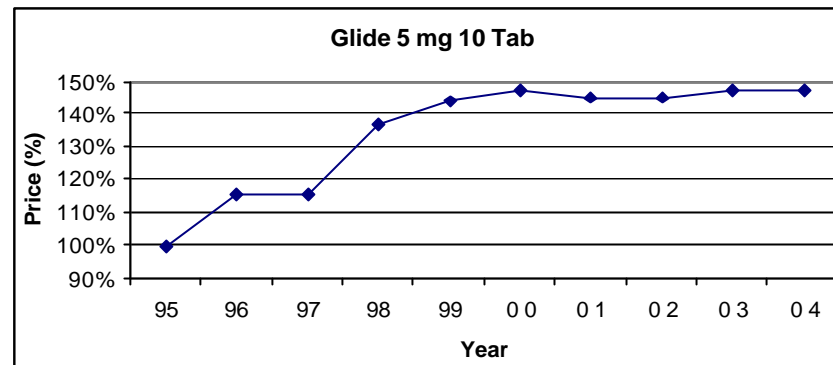
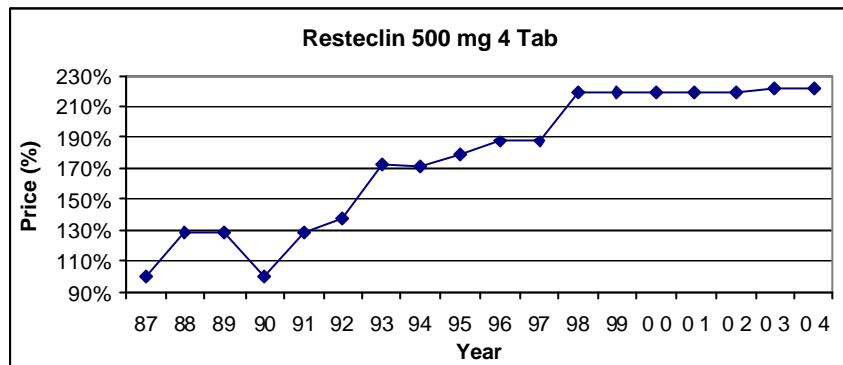
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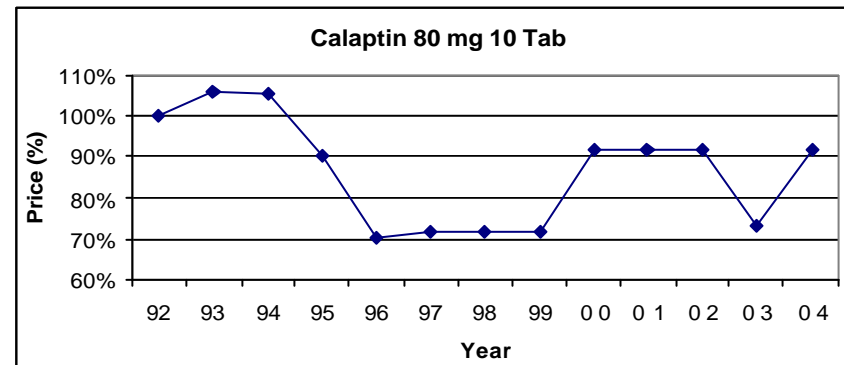
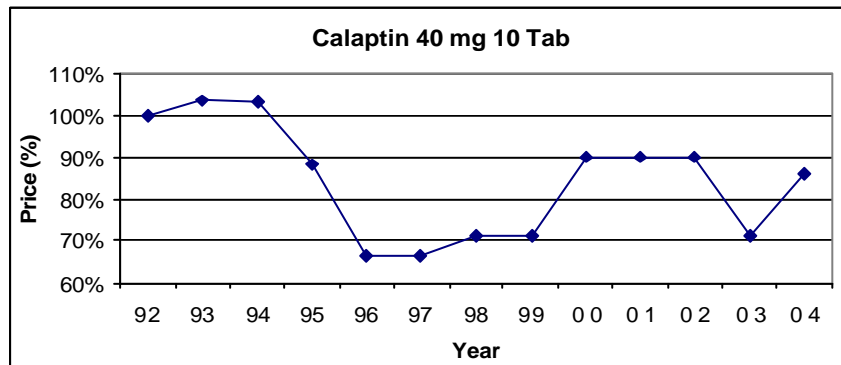
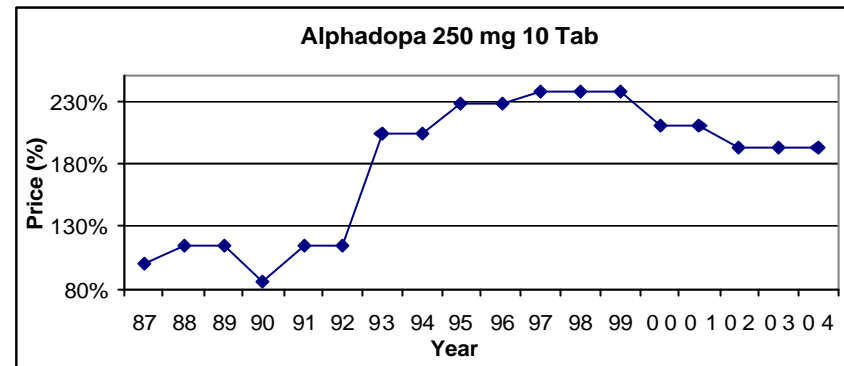
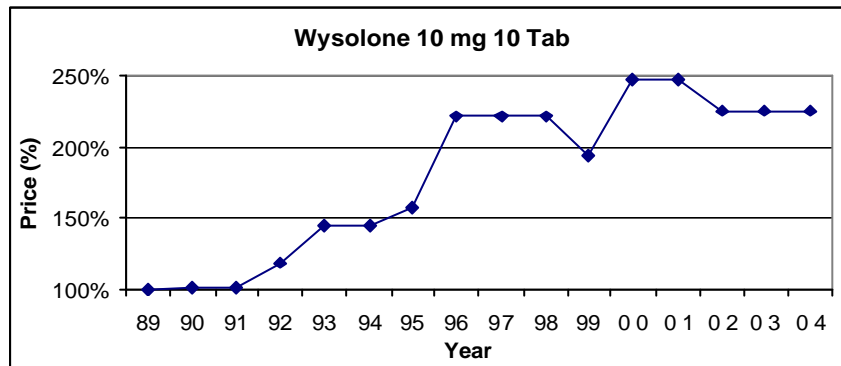
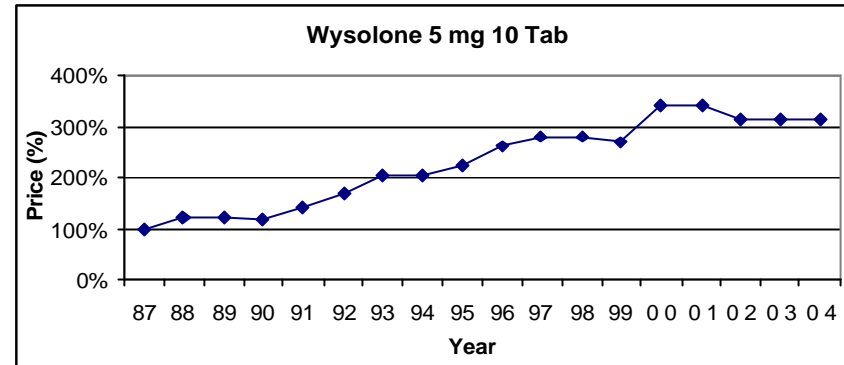
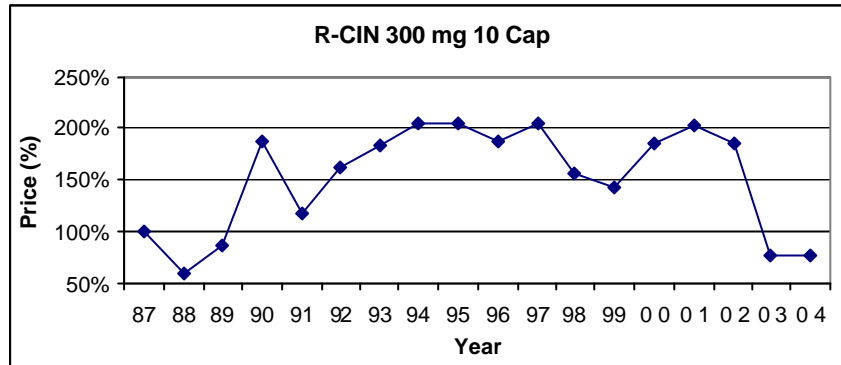


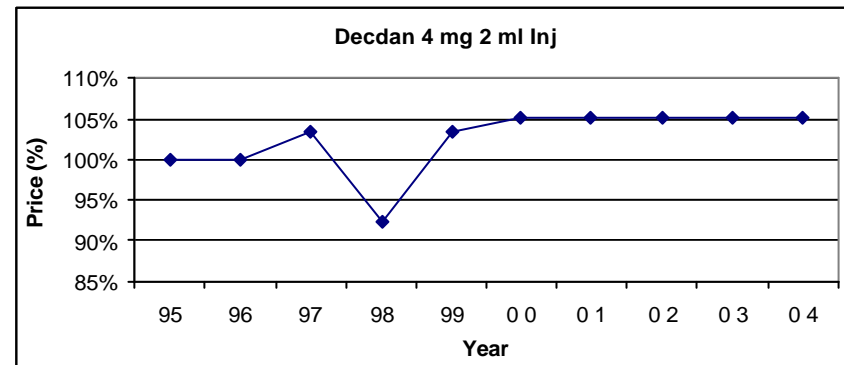
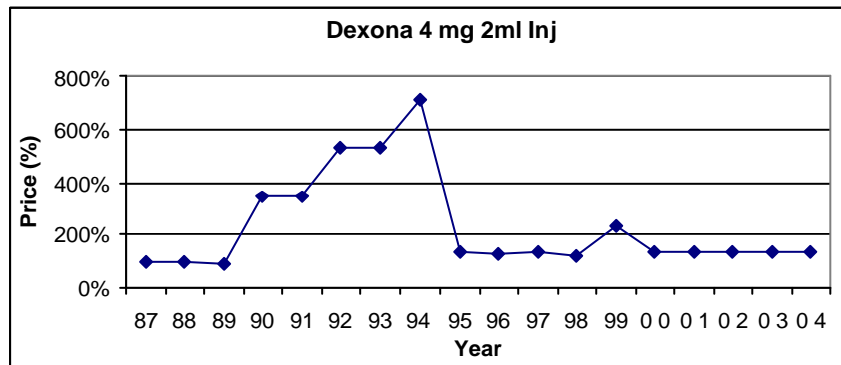
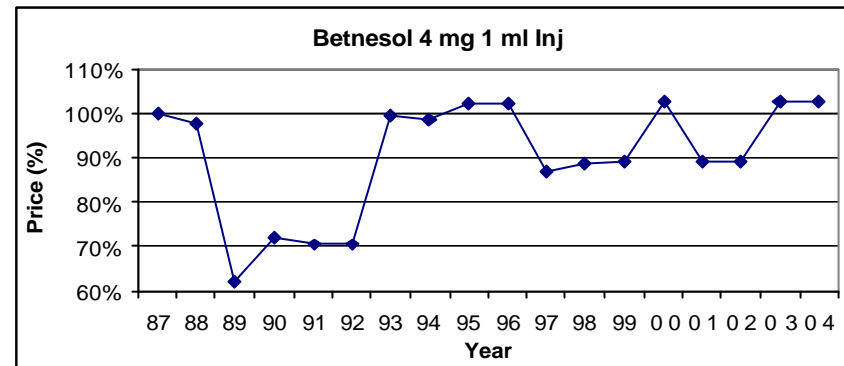
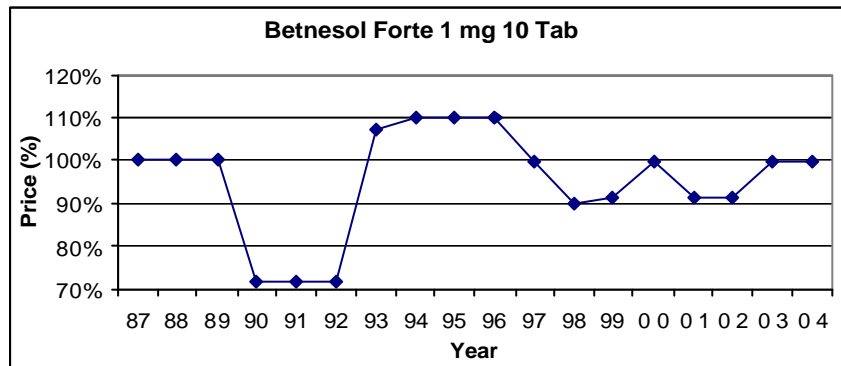
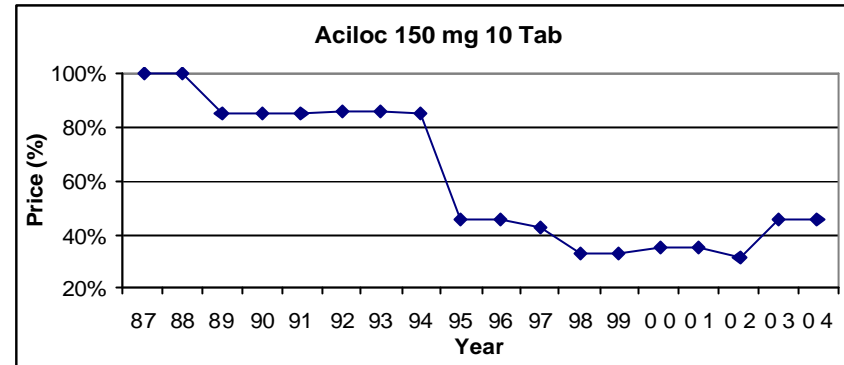
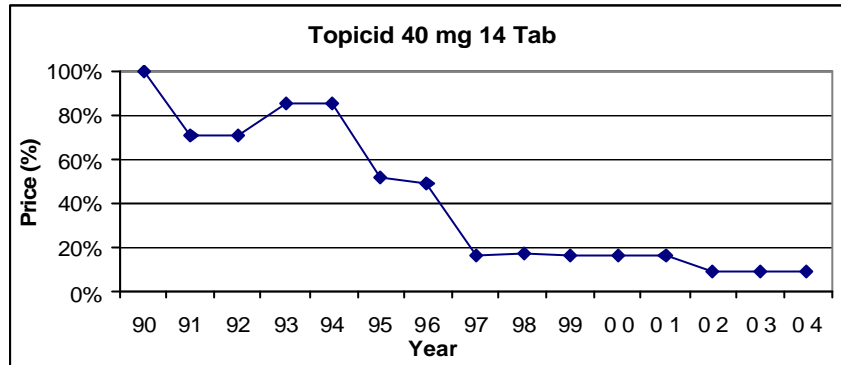


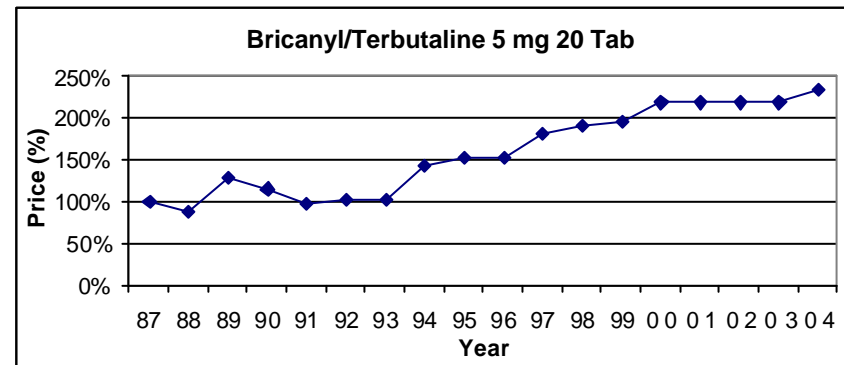
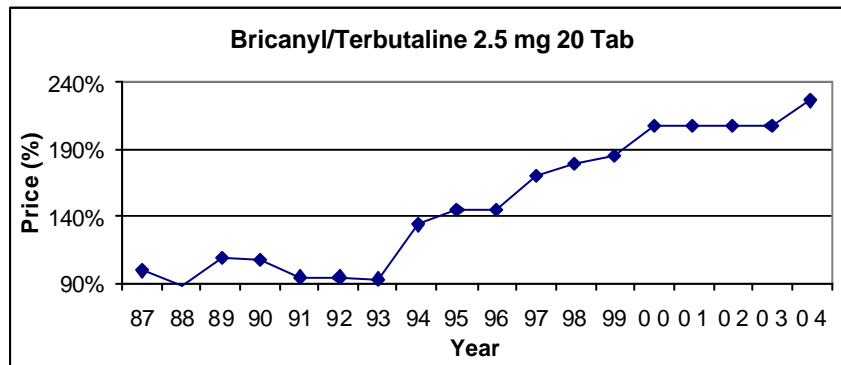
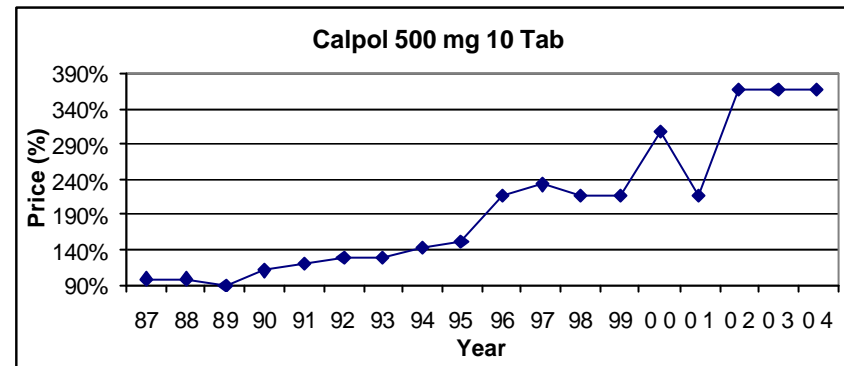
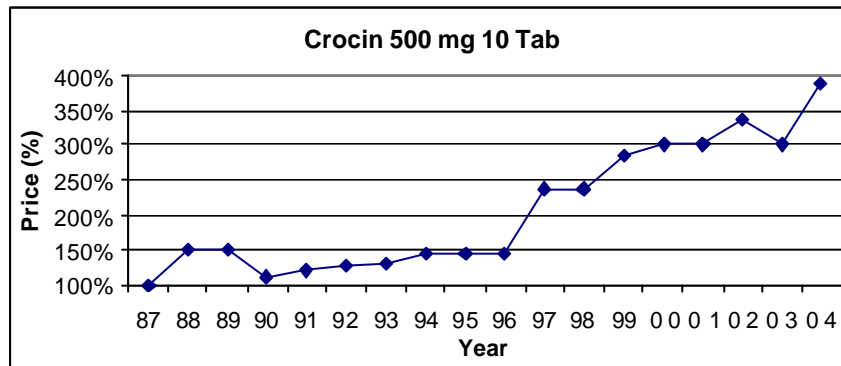
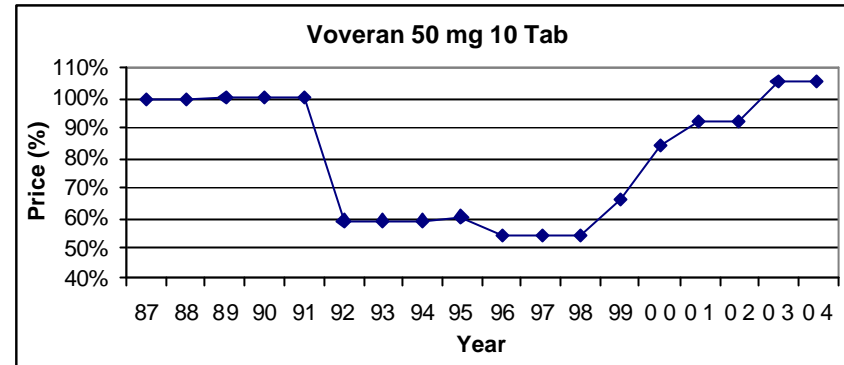
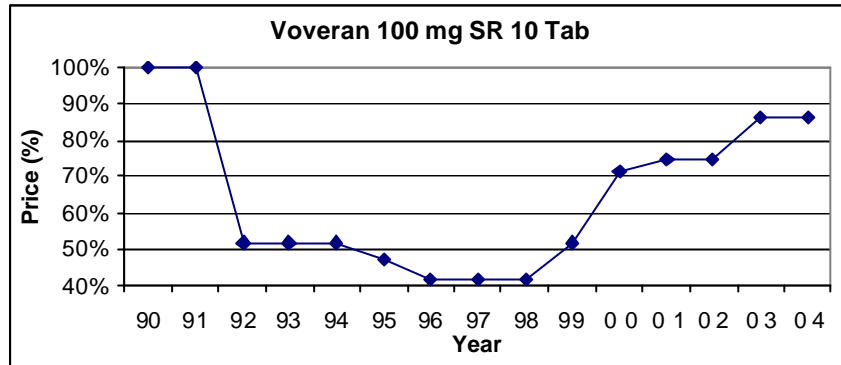


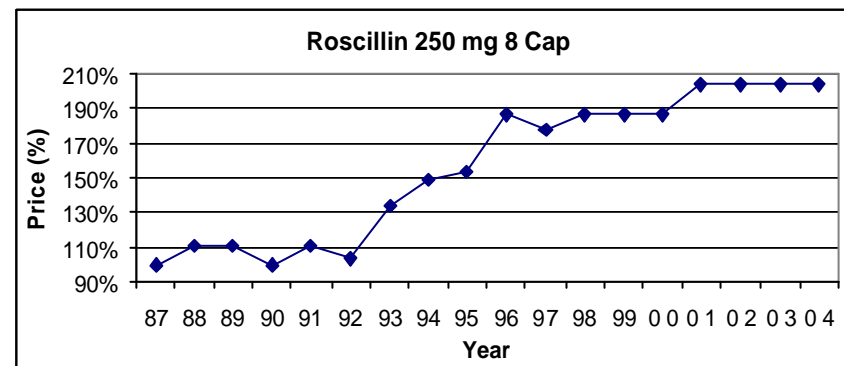
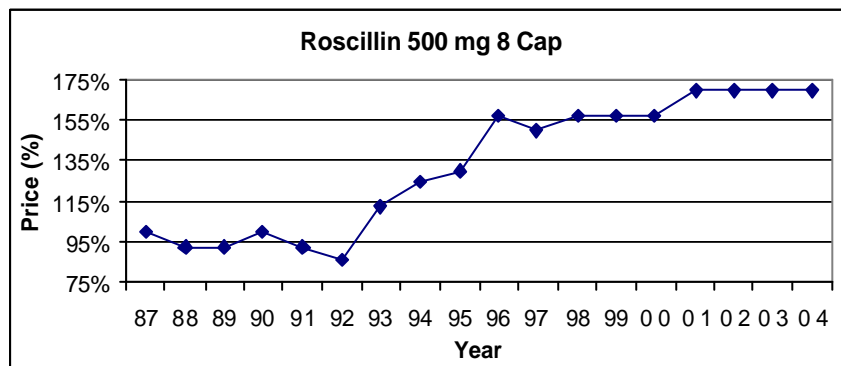
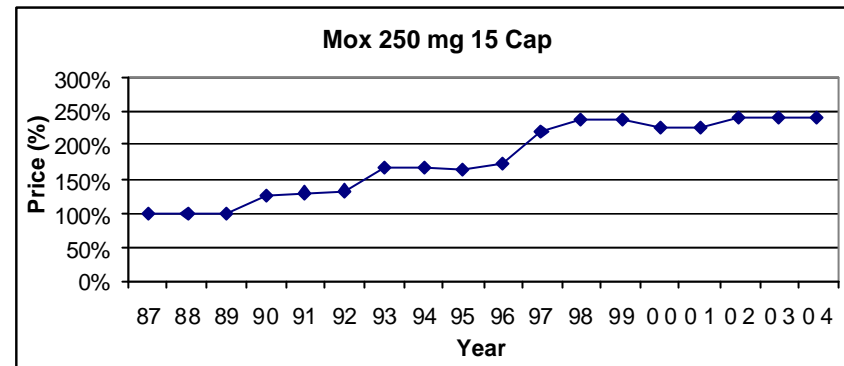
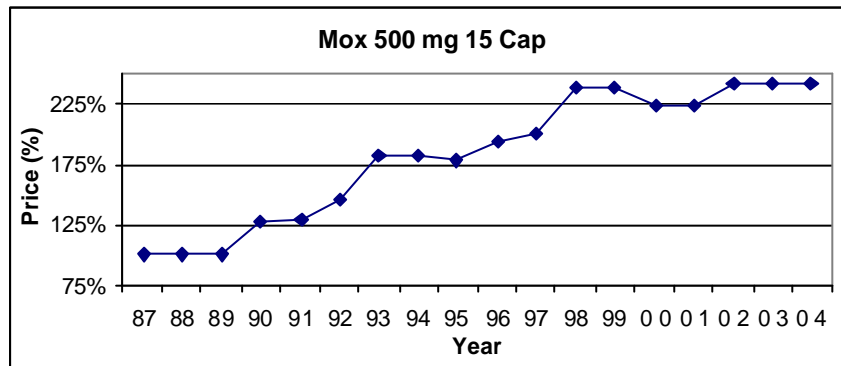
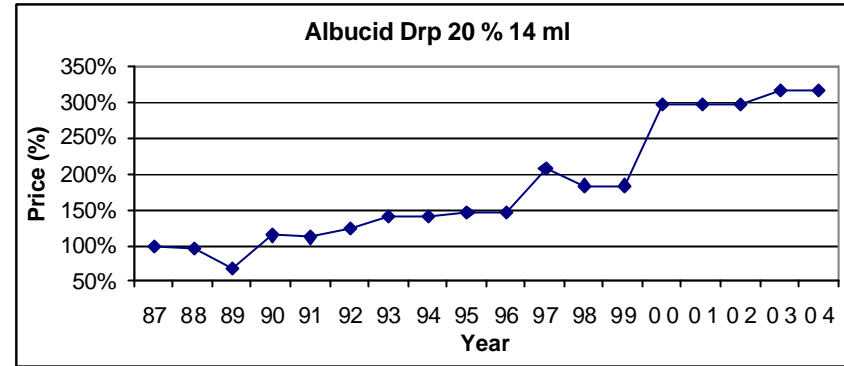
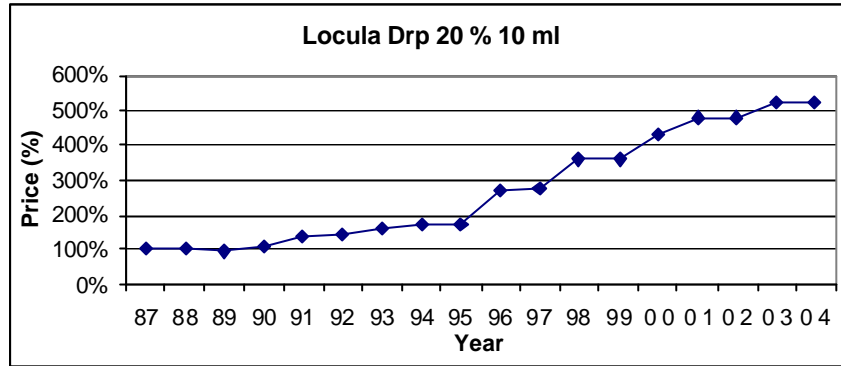


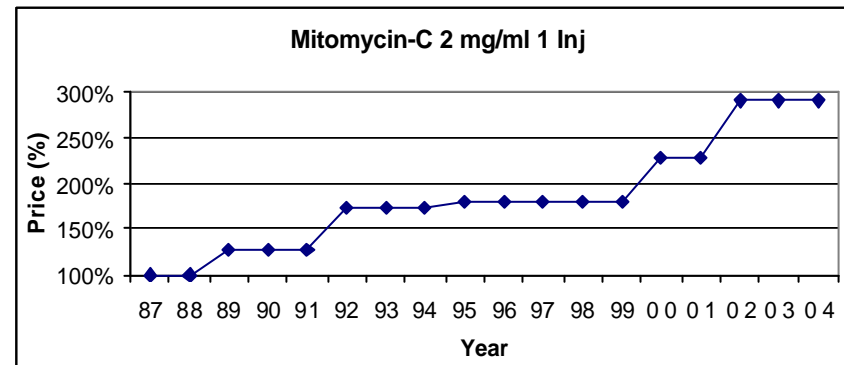
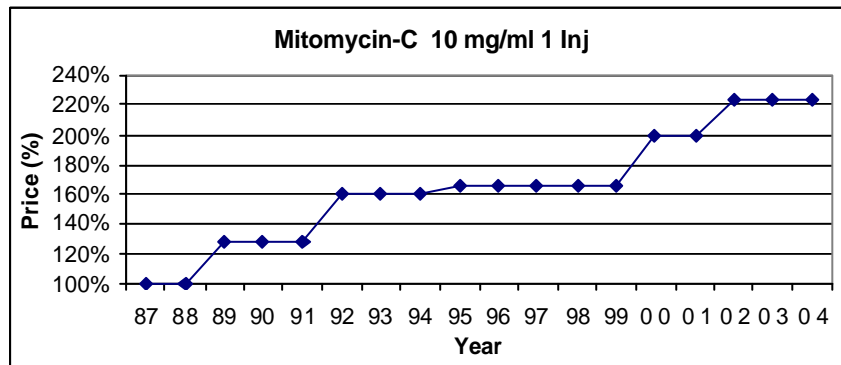
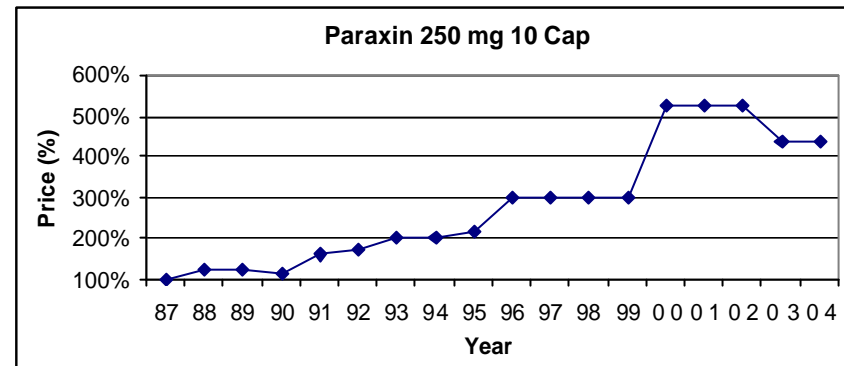
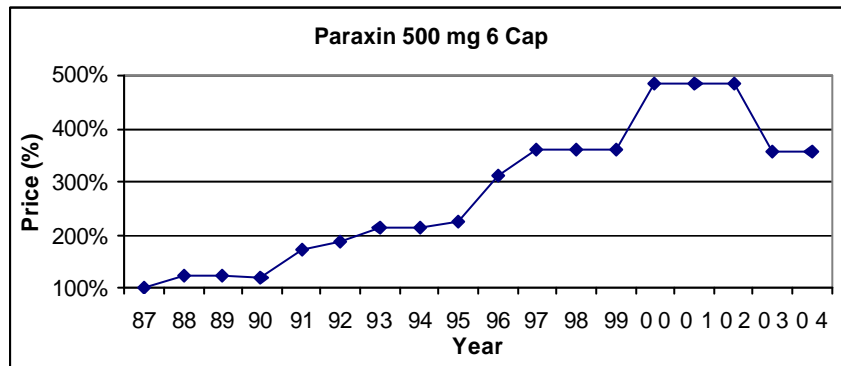
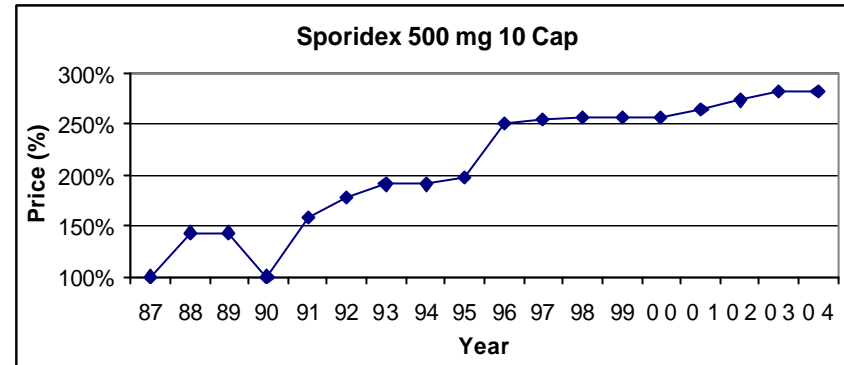
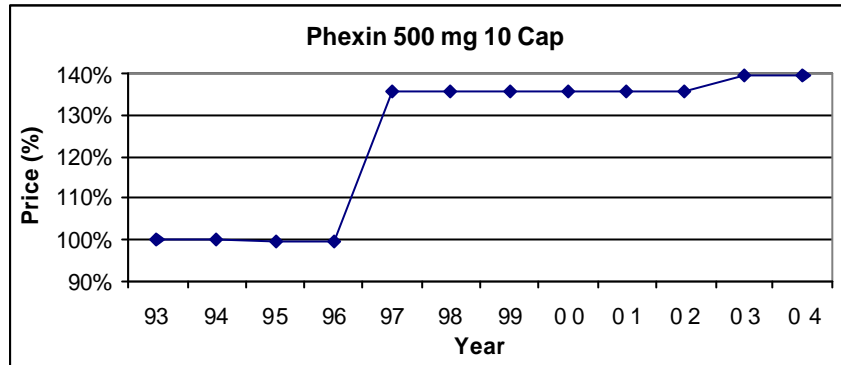


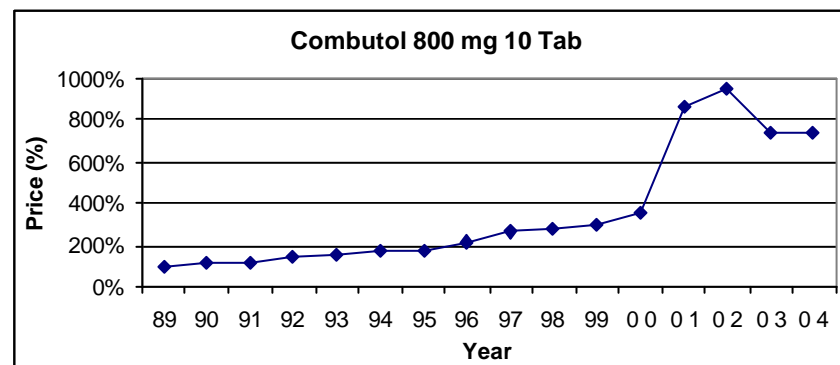
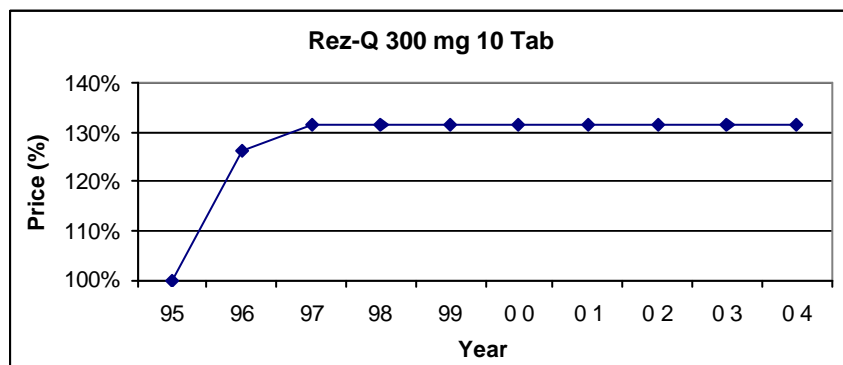
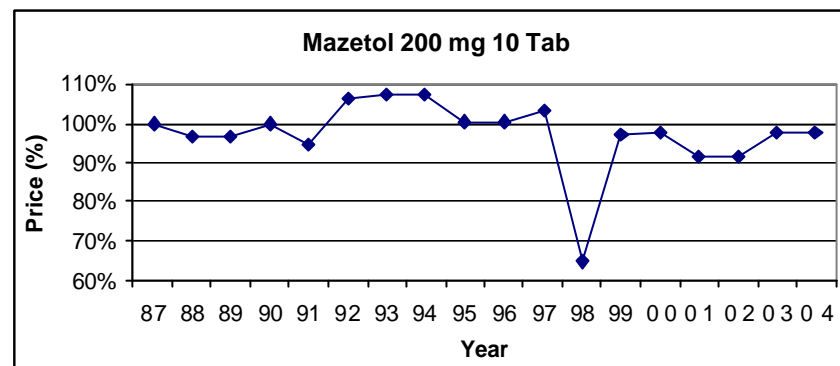
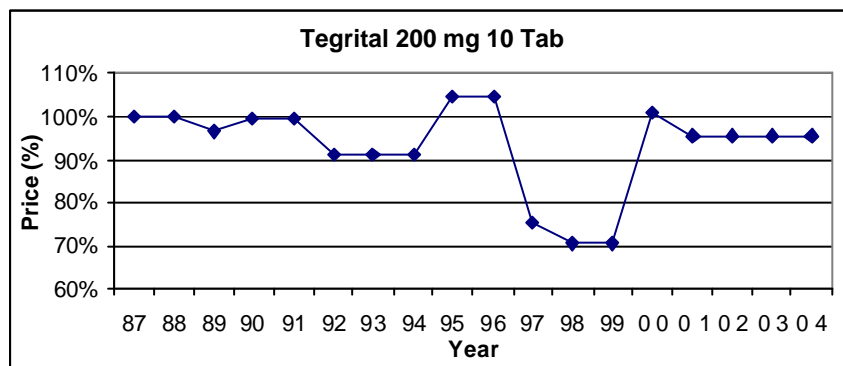
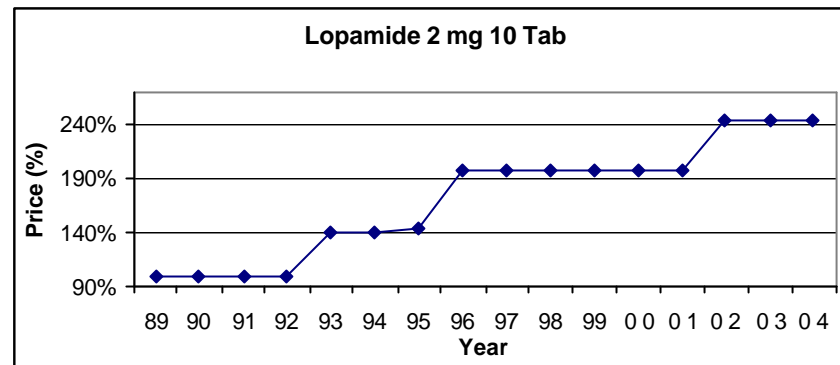
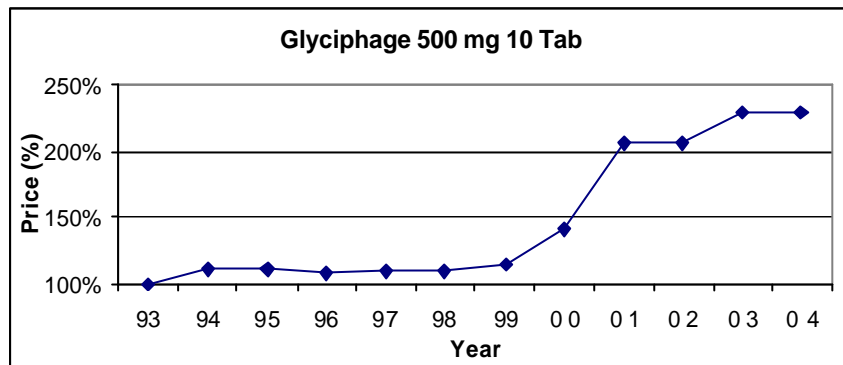


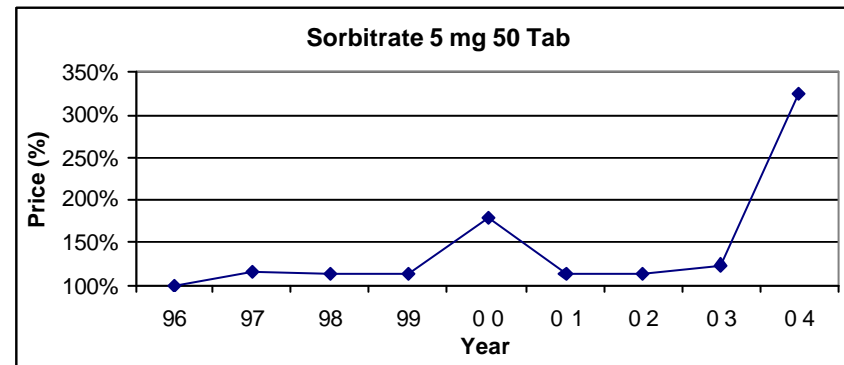
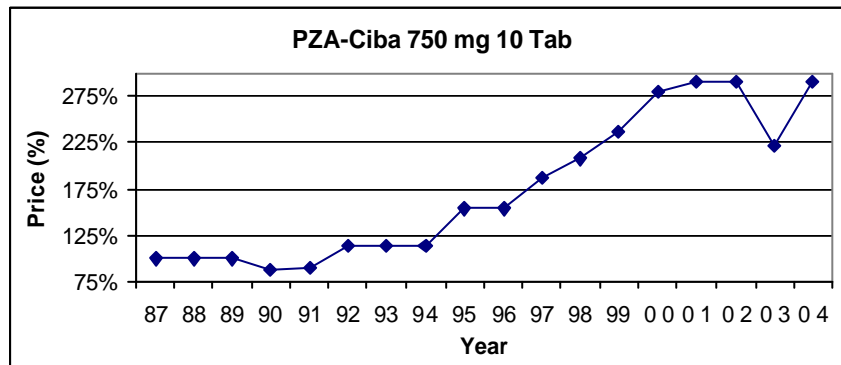
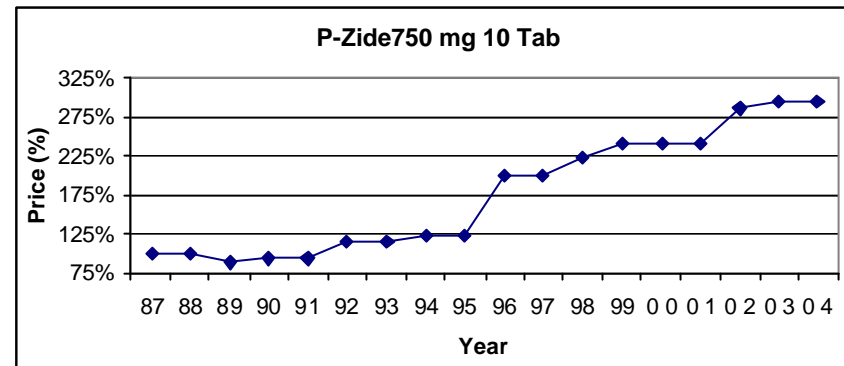
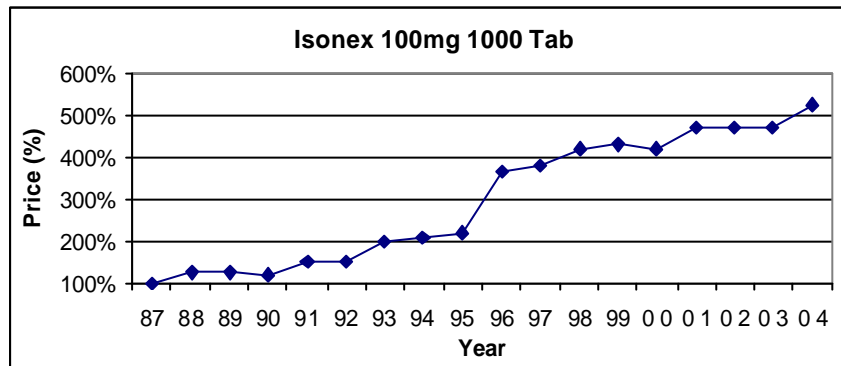
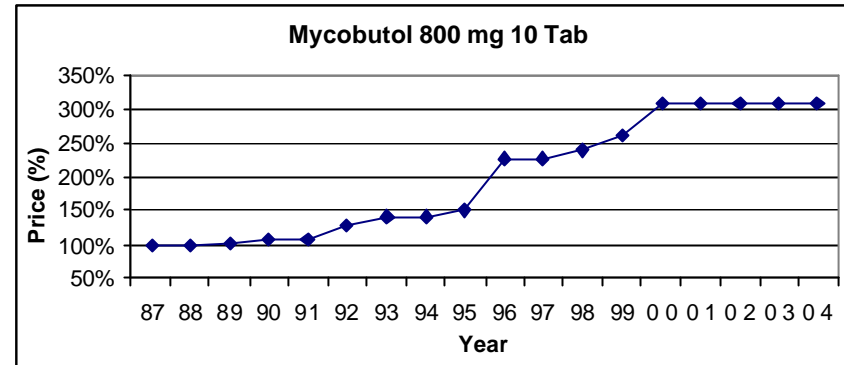
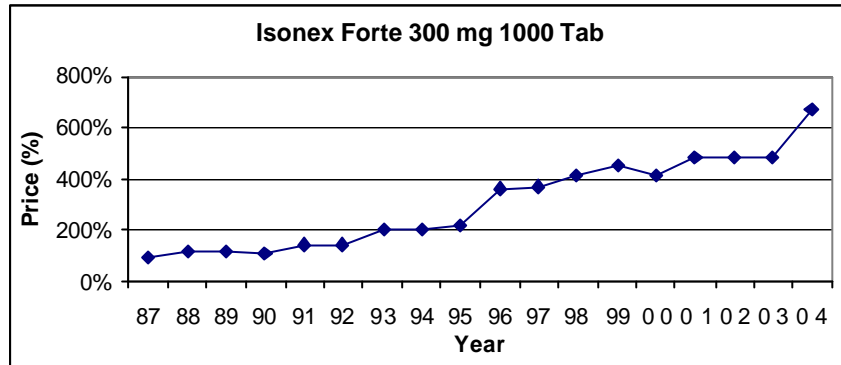


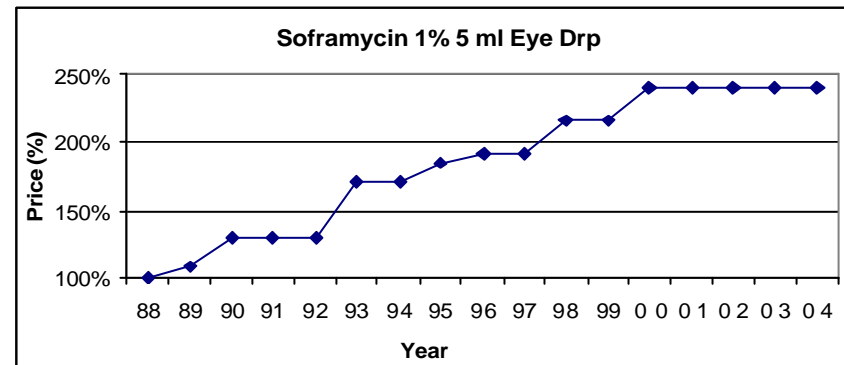
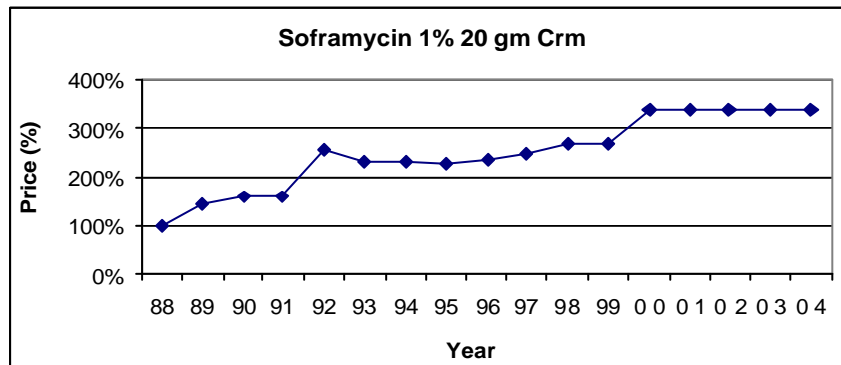
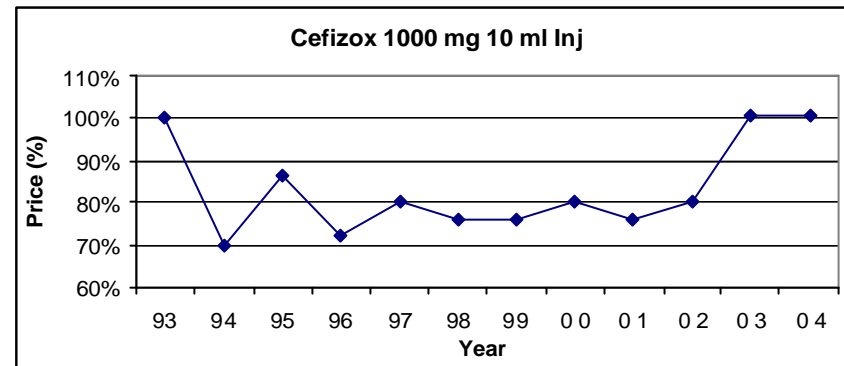
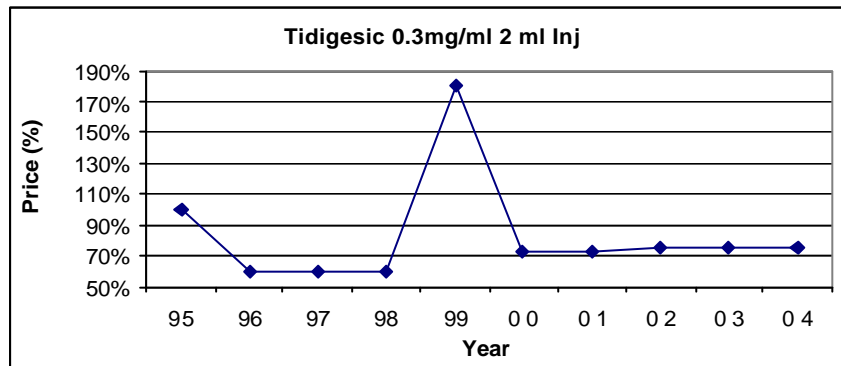
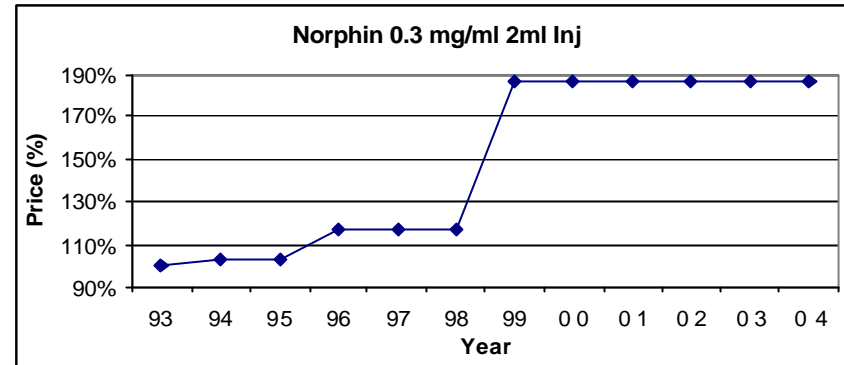
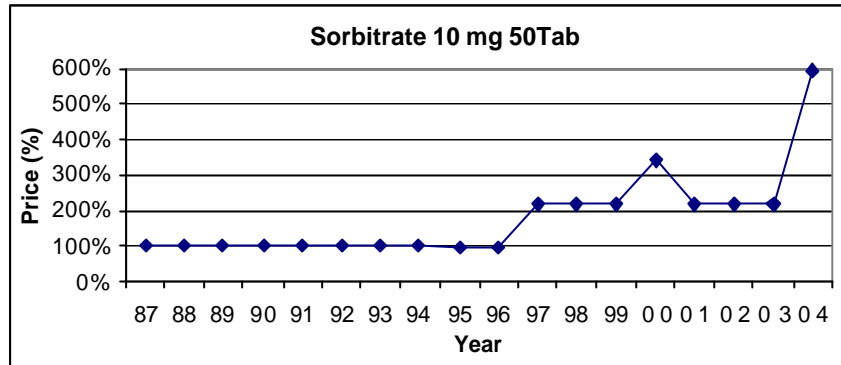


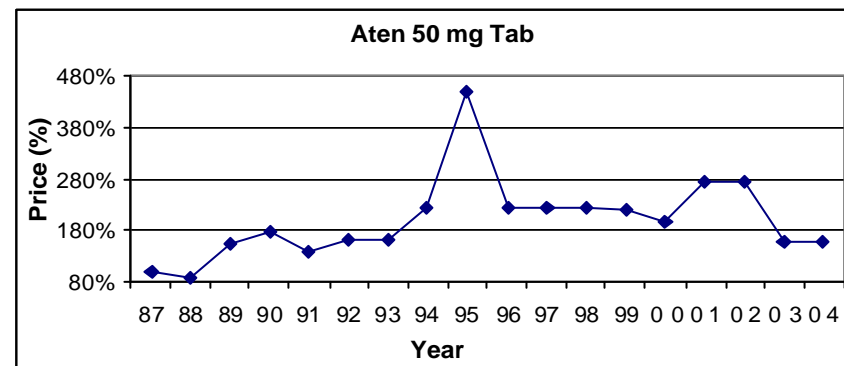
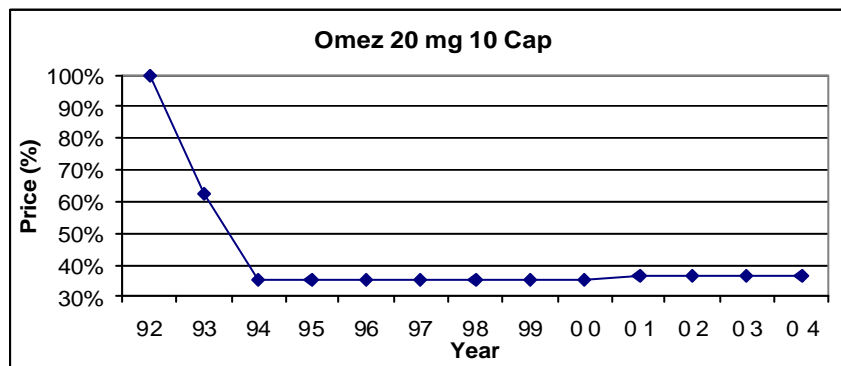
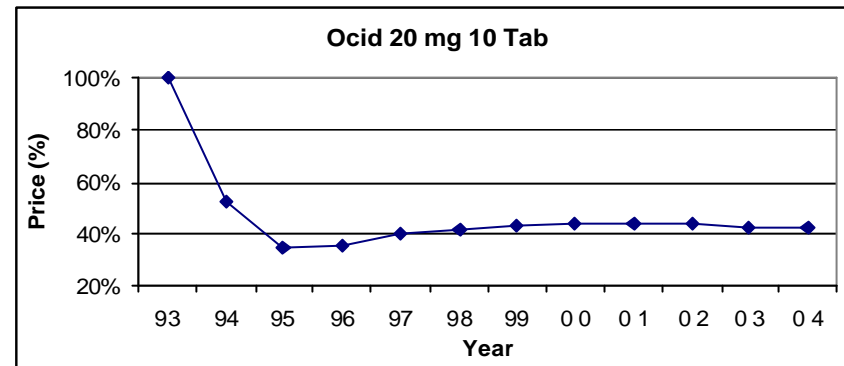
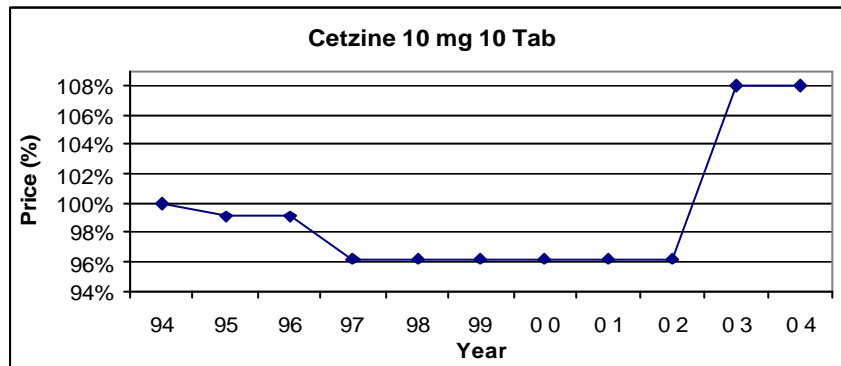
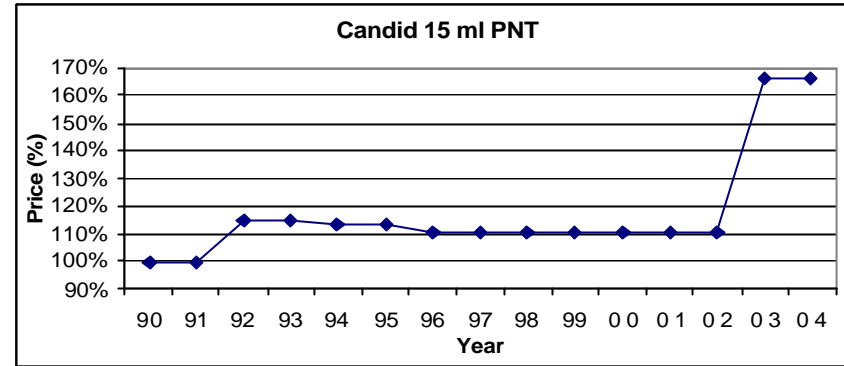
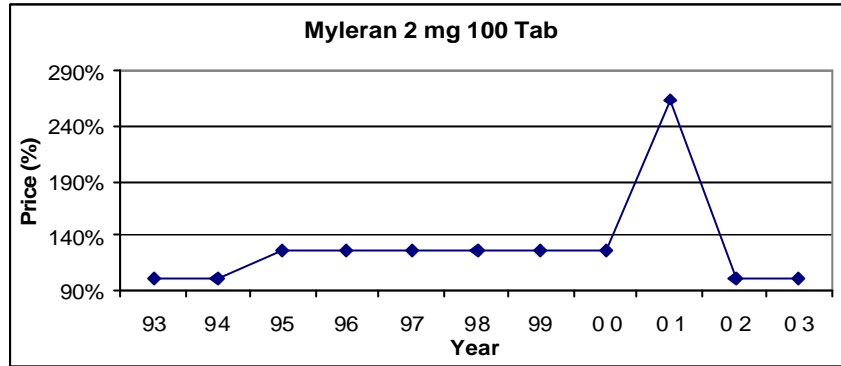


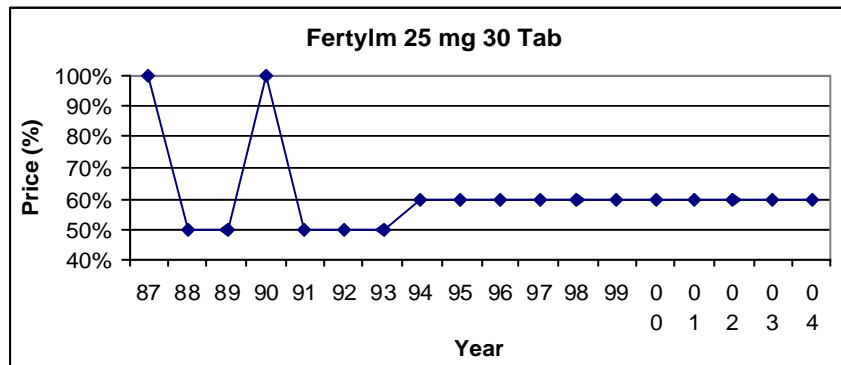
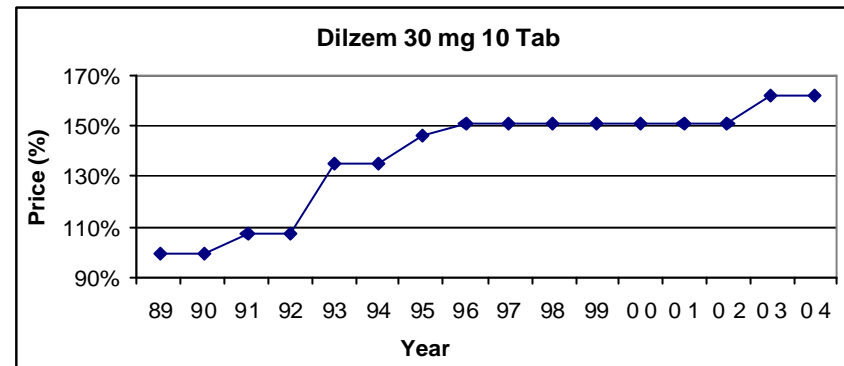
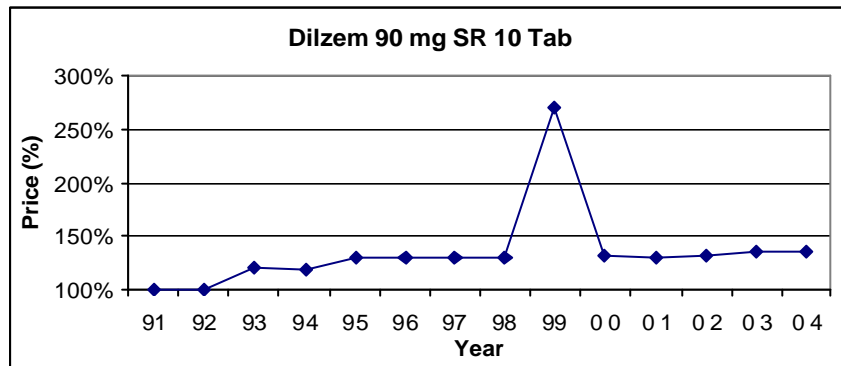
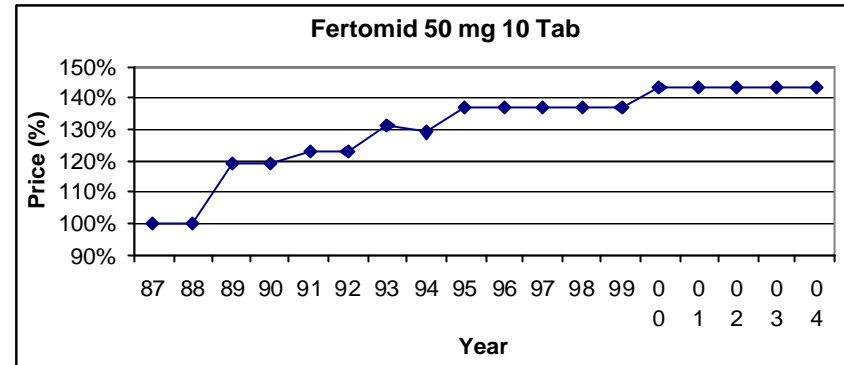
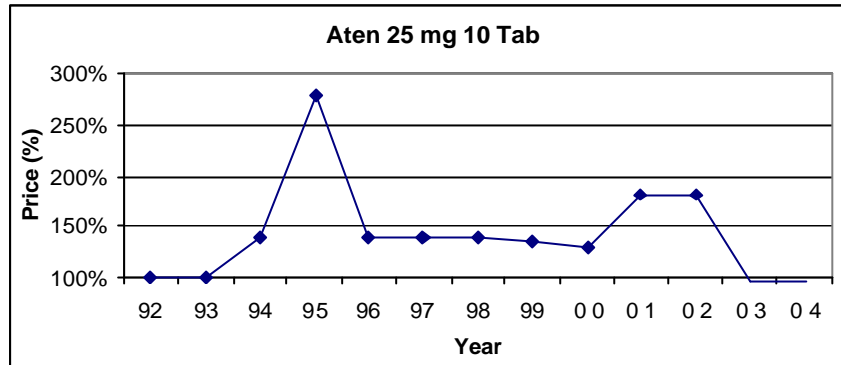












## 10.4 Annexure-4

### List of resource persons in the first workshop

1. Dr. Nitya Nand
2. Dr. N. K. Ganguly
3. Dr. H. P. S. Chawla
4. Dr. Amarjit Singh
5. Dr. H. R. Bhojwani
6. Dr. Dinesh Abrol
7. Dr. Amitava Guha
8. Dr. A. D. Damodaran
9. Mr. G. Wakankar
10. Prof. A. K. Gupta
11. Dr. Amit Sengupta
12. Dr. Naresh Kumar

## 10.5 Annexure-5

**Program for the INPUTS WORKSHOP on  
IMPACT OF TRIPS ON PHARMACEUTICAL PRICES  
Feb 14, 2005 at NIPER**

Time	Particulars	Remarks
0920-1015	Inaugural function	
1015-1100	High Tea	
1100-1230	<p><b>Session I:</b> TRIPS &amp; its impact on Pharmaceutical R &amp; D</p> <p style="text-align: right;"><i>Rapporteur: Dr. P. Bansal</i></p> <ul style="list-style-type: none"> <li>• Dr. N. K. Ganguly</li> <li>• Dr. H. P. S. Chawla (Impact of TRIPS on Pharma Research)</li> <li>• Dr. Amarjit Singh (TRIPS and its impact on Pharmaceutical R &amp;D)</li> <li>• Dr. H. R. Bhojwani (Japan Inc. Breached : India alerted?!)</li> </ul>	
1230-1345	Lunch	
1345-1515	<p><b>Session II:</b> TRIPS &amp; its impact on Pharmaceutical prices</p> <p style="text-align: right;"><i>Rapporteur: Ms. P. Garg</i></p> <ul style="list-style-type: none"> <li>• Dr. Dinesh Abrol</li> <li>• Dr. Amitava Guha (TRIPS Agreement and Pharmaceutical Pricing)</li> <li>• Dr. A. D. Damodaran (The SWOT Analysis of Patents Ordinance 2004 – a case study)</li> </ul>	
1515-1530	Tea/coffee break	
1530-1700	<p><b>Session III:</b> TRIPS &amp; its impact on drug availability</p> <p style="text-align: right;"><i>Rapporteur: Dr. P. Tiwari</i></p> <ul style="list-style-type: none"> <li>• Mr. G. Wakankar (Impact of TRIPS on Pharmaceutical Prices)</li> <li>• Prof. A. K. Gupta (TRIPS &amp; its impact on drug availability)</li> <li>• Dr. Amit Sengupta (Manufacture of Generic Drugs in India post 2005 Scenario)</li> </ul>	
1700-1730	<b>Concluding session</b> {co-ordinated by Dr. Naresh Kumar}	

## 10.6 Annexure- 6

**Program for the DISSEMINATION WORKSHOP ON  
IMPACT OF TRIPS ON PHARMACEUTICAL PRICES**

**Saturday, 22nd April, 2006 at NIPER**

<b>Time</b>	<b>Particulars</b>	<b>Remarks</b>
10:30-11:00	Registration	
<b>11:00-11:30</b>	<b>High Tea</b>	
11:30-11:40	Welcome address- Prof. P.Rama Rao, Director, NIPER	
11:40-12:15	Inaugural address- Mr.Rajesh Bhushan, IAS, Director, MOHFW, New Delhi	
12:15-12:20	Vote of thanks- Dr.Pramil Tiwari, Pharmacy Deptt. NIPER	
12:20-13:10	<b>Technical Session I:</b> "TRIPs, Doha Development Round and Life beyond 2006" <i>Dr.Naresh Kumar, Head, RDPD, CSIR HQ, New Delhi</i>	
<b>13:10-14:00</b>	<b>LUNCH</b>	
14:00-15:00	<b>Technical Session II:</b> " Impact of TRIPS on Pharmaceuticals in India, with specific focus on Generics" <i>Dr. Parikshit Bansal, IPR and Technology Cell, NIPER</i>	
<b>15:00-15:30</b>	<b>Session Tea</b>	
15:30-16:00	<b>Technical Session III:</b> "Review of the Drug Procurement Systems" <i>Dr. P. Tiwari, Pharmacy Deptt., NIPER</i>	
16:00- 16:30	<b>Technical Session IV:</b> "Overview of the mechanisms for pricing of drugs" <i>Mrs. Prabha Garg, NIPER</i>	
16:30- 17:00	<b>OPEN QUESTION AND ANSWER SESSION</b>	
17:00- 17:15	<b>Concluding remarks by Dr.P. Rama Rao*</b> <i>* Originally scheduled to be delivered by representative of WTO cell.</i>	

## 10.7 Annexure-7

## List of resource persons in the dissemination workshop

List of Invited Participants

S.No.	NAME
1	<b>Mr. Ujjwal Kumar</b> , National Consultant, WTO cell, International Health Division, MOHFW, New Delhi
2	<b>Mr. Rajendra Mehrotra</b> , National Consultant, WTO cell, International Health Division, MOHFW, New Delhi
3	<b>Dr. Naresh Kumar</b> , Head, RDPD, CSIR HQ, New Delhi
4	<b>Dr. A. K. Gupta</b> , Medical Supttd. and Prof. Hospital Administraton, PGIMER, CHD
5	<b>Dr. Naresh Kumar</b> , GM, Ranbaxy Labs Ltd., Mohali
6	<b>Mr. Rajive Goel</b> , GM (International Business)Venus Remedies, Panchkula
7	<b>Mr. Sukant Gupta</b> , Ex Deputy Advocate General, Punjab Govt. and Practising Lawyer, Punjab and Haryana High Court, Chandigarh
8	<b>Ms. Jaswinder Kaur</b> , Principal, SGGGS College of Pharmacy, Sector 26, Chandigarh
9	<b>Mr. Sanjay Bajaj</b> , Lecturer, SGGGS College of Pharmacy, Sector 26, Chandigarh
10	<b>Mr. Lalit Kaushal</b> , National Pharmaceutical Pricing Authority, New Delhi
11	<b>Mr. N.I. Chaudhury</b> , National Pharmaceutical Pricing Authority, New Delhi
12	<b>Mr. Sunil Nandraj</b> , National Professional Officer, WHO India Office, New Delhi
13	<b>Ms. Anagha</b> , National Consultant, WHO India Office, New Delhi
14	<b>Mr. Avinash Mathur</b> , Ex-President, Philips India Ltd. And presently Quality Consultant, Chandigarh.
15	<b>Dr. Sanjay Kaushik</b> , Reader, University Business School, Panjab University, Chandigarh

<b>S.No.</b>	<b>NAME</b>
16	<b>Dr. Gurbir Singh</b> , Medical Director, Fortis Multispeciality and Heart Centre, Mohali
17	<b>Dr. Vipin Kaushal</b> , Deputy Medical Superintendent, Nehru Hospital, PGIMER, Chandigarh
18	<b>Dr. B. B. Tandon</b> , Ex-Chairman, University Business School, Panjab University, Chandigarh
19	<b>Mr. Sakthivel</b> , Research Fellow, Instt. For Human Development, New Delhi.
20	<b>Dr. S K Mangal</b> , Centre for Rural and Industrial Development, Sector 7, Madhya Marg, Chandigarh
21	<b>Prof. V R Sinha</b> , Professor, University Institute of Pharmaceutical Sciences, Chandigarh
22	<b>Dr. Mrs. Kirandeep Kaur</b> , Sr. Resident, Govt. Medical College and Hospital, Chandigarh
23	<b>Col Angad Singh</b> , General Secretary, Consumer Protection and Grievances Redressal Forum, Mohali
24	<b>Ms Neena Bedi</b> , Reader, Department of Pharmaceutical Sciences, Guru Nanak Dev University, Amritsar
	TOTAL- 24

## **10.8 Annexure- 8**

### **PROCEEDINGS OF THE TRIPS DISSEMINATION WORKSHOP HELD AT NIPER, 22ND APRIL, 2006**

Nearly seventy five people participated in the workshop and various technical sessions. List of the invited experts is enclosed at Annexure-1.

The welcome address was delivered by Dr.P.Rama Rao, Director, NIPER, Mohali and inaugural address by Mr.Rajesh Bhushan, Director, Ministry of Health and Family Welfare, New Delhi.

Four technical sessions were conducted by the following experts:

1. Dr.Naresh Kumar, Head, RDPD, CSIR HQ, New Delhi,
2. Dr.Parikshit Bansal, Asstt. Prof. (Intellectual Property Management), I/C IPR and Technology Cell, NIPER
3. Dr.Pramil Tiwari, I/C Pharmacy Practice, NIPER
4. Ms.Prabha Garg I/C Computer Centre, NIPER

#### **Technical Session 1**

Dr. Naresh Kumar in his talk on “TRIPs, Doha Development Round and Life beyond 2006” spoke of the effect which TRIPs provisions are going to bring on to the pricing of patented pharmaceutical products in India.

He enumerated the events which led to the signing of TRIPs Agreement and subsequent deliberations in the Ministerial conferences. TRIPs Agreement which is by far the most far reaching multilateral agreement ever negotiated on intellectual property. It has tried to establish minimum universal standards on all aspects of intellectual property. This agreement is of interest not only to IPR specialists but has equal relevance to political and social systems. It has tried to strike a balance between the short-term interests in maximizing access and long term interests in promoting creativity and innovation. Its ostensible purpose is promoting R&D in new drugs and making available the existing drugs at affordable prices.

According to Dr. Naresh, although initially the developing nations could not comprehend the full implications of TRIPs but beginning with Doha Round, the developing world has pitched with the developed world to bring in a balance between public and private interests. TRIPs evokes strong reactions both for and against. Although the issues related to pharmaceuticals

are now well-settled, the issues related to other aspects of Doha Development Round like agriculture, service, trade rules are yet to be settled.

India which is now fully TRIPs compliant, shall have to monitor very closely its impact on prices of new drugs especially when drugs under 'mail-box arrangement' are examined and granted. In this connection NIPER's study is very timely. Its prophesy that TRIPs is unlikely to affect the prices of drugs in the times to come needs to be very closely watched.

## **Technical Session 2**

Dr. Parikshit Bansal in his presentation entitled " Impact of TRIPS on Pharmaceuticals in India, with specific focus on Generics" gave a summarized presentation of the overall study-methodology used and interpretation of the results. Major points made during the presentation are as follows:

- Ten years of data (1996-2005) on drug prices in various categories (antibiotics, antiulcer, cardiac care, antihistamine, anti-TB, anti-malarial, anti-AIDS, anti-Cholera and antifungal) was compiled. In addition to price data, data on number of manufacturers in each category was also compiled.
- It was found that so far there has been no significant increase in drug prices in the post-TRIPS period (1996-2005). Rather, there was a distinct fall in prices of some of the drugs.
- Since product patents in India came into force w.e.f. 1<sup>st</sup> Jan. 2005, the drugs prior to this can be classified as 'generic' drugs for all practical purposes.
- Regarding stability in prices of drugs, it could be attributed to presence of a strong indigenous manufacturing base which ensured that prices remained stable and low as compared to those sold by multinational companies. In fact, almost all the generic drugs being manufactured by multinationals are being produced indigenously too.
- Regarding, fall in prices after TRIPS, rather than increase, a plausible factor was increased competition as indicated by increase in number of manufacturers in some categories of drugs e.g. number of manufacturers of the antibiotic Oflaxacin jumped from only 3 in 1996 to 60 by the year 2005. The average prices for a four tablet pack of 200 mg of the same fell from Rs.94/- in 1996 to only Rs. 19/- by 2005. For Norfloxacin, 400 mg (10 tablets), average prices over a ten year period fell by almost 50% (Rs. 42/- in 1996 to Rs.22/- in 2005), whereas the number of manufacturers remained unchanged.
- In fact average prices of all antibiotic formulations under study, showed a distinct fall over a ten year period rather than increase.
- In other categories also, prices either remained stable or fell, but showed no significant increase.
- This indicates that technological advancements in the manufacturing process are also a significant factor in affecting prices, apart from competition. It is important to mention that quite often, Indian manufacturers freely carried out innovations and improvements in processes resulting in decreased production costs, whereas multinationals hesitated to experiment with new and often more efficient processes

because in their countries, adoption of new processes for making drugs also required approval, which was sometimes quite a long and expensive process.

- Based on analysis of data and other related aspects, a simple model ‘NIPER 2D Model’ on ‘drug prices’ was proposed in the study.
- According to this model, the prevailing prices of widely used drugs in any country can be attributed to two distinct parameters - *Technological Strengths and Socio-economic factors* rather than TRIPS or product patents alone. Countries which are not technologically sound (strong pharma industry absent) and are dependent on imports, suffer from high prices of drugs. India too was one such country, following the initial years after independence. Though it was socio-economically weak, still drug prices were not low owing to lack of technological strength. However, once self-reliance in pharma production was achieved, prices fell dramatically even in the post-TRIPS period. Thus “Technological Strength” is the first dominant factor which influences drug prices.
- Secondly, socio-economic conditions also play a key role in influencing drug prices. In India, vast majority of the population cannot afford even generic drugs, let alone high priced patented medicines, since there is no system of healthcare coverage of the population as prevalent in western countries. Hence, the Indian pharma industry is ‘production oriented’ –focussing on bulk production at cheaper cost, by developing new and improved processes, rather than trying to develop new molecules. A large booming population ensures a market for low-priced generic medicines, which are not affected by TRIPS or changes in patent laws.
- Based on results of the study, it was concluded that TRIPS is unlikely to have an affect on the prices of existing drugs in the times to come, owing to technological strengths of the indigenous pharma industry and the peculiar socio-economic conditions of the country where generics command a significant chunk of the market.
- Based on the study undertake, it was recommended that the Indian pharma industry should focus on developing competence in advanced areas of drug manufacture e.g. biopharmaceuticals, DNA based drugs etc. in which its technological strength is low.
- After TRIPS, prices of traditional chemical drugs are likely to remain stable and possibly even fall rather than rise, owing to infusion of better and state-of-the-art manufacturing capabilities by the domestic pharma industry. The fact that outside the United States, the highest number of FDA compliant manufacturing units is in India supports this view.
- However, for biological drugs (e.g. erythropoetin, insulin, gamma IgG, Colony stimulating factor, interleukins etc.) prices are likely to remain high owing to absence/limited domestic competition. Interestingly, several of the patented biodrugs themselves are falling into the ‘generics’ category, their patents having expired or being on verge of expiry. But their prices are not likely to come down in the near future, owing to absence of domestic challenge. Hence, it is imperative that the pharma industry and the Indian government recognize this challenge and go into mission mode to bridge this gap.
- The study also revealed that the India pharma industry has been wrongly criticized for not carrying out R&D. It is by no means a small achievement to bypass a highly technical manufacturing patented process (process patents were allowed in India even before TRIPS, though of limited duration) developed by technologically superior countries! The fact that the Indian Pharma Industry was successfully able to meet the

challenges of developing better, more efficient processes is a tribute to its R&D capabilities.

- The hard fact is that the prevailing socio-economic conditions in the country did not permit the industry with its limited resources to 'hunt' for fancy, new molecules. Rather, the population and socio-economic conditions created a demand for R&D which would result in faster production of existing drugs at lower costs. The industry met that challenge by developing new, non-infringing processes for manufacturing drugs.
- In this context, an important observation was made by Dr. Bansal. It was clarified that patents are granted for only two categories- products or processes and there is no third category. Too much focus (and fear) had been generated due to product patents. However, generics (which commanded a major share of the market in India) are not affected by product patents. Rather they are affected by 'process patents', since a new improved process could significantly affect prices. Under the TRIPS agreement, the term of the process patents for drugs has been increased to 20 years from the earlier duration of only 7 years. However, this in turn is beneficial in public interest, because an improved process is aimed at better efficiency and lowering costs. Hence, it would lead to lowering of costs of drugs and not increasing them! Secondly, the affected party would be the domestic industry and not the general public. Here too, there is not much cause for concern. The Indian Pharma industry has proven time and again that it has the capability to 'invent around' and develop non-infringing processes. In the event of a new process being developed and patented, once the information comes into the public domain, there is a strong possibility that the process will be improved further and a non-infringing process developed or the new process got patented by the industry itself!
- Given the vast storehouse of traditional knowledge, some of it exclusive to India, the excellent research infrastructure facilities and large pool of trained human resources available to the pharma industry, there stands nothing in the way of the industry to go in for new drug discovery, development of new systems of drug delivery and also new generation of drugs. TRIPS rather than being a barrier, offered new opportunities to the Industry in tapping not only domestic but also global markets, by seeking intellectual property protection for their own innovations and discoveries.

### **Technical Session 3**

Dr. P. Tiwari, in his presentation entitled "Review of the Drug Procurement Systems", mentioned that the three objectives that need to be addressed in the overall management of a drug policy are –

- a) All essential drugs needed for health care should be available at all the times at all the health facilities;
- b) Drugs so made available should be of good quality and should be safe; and, finally
- c) The systems of procurement should be such that quality drugs are procured at the most competitive prices.

1. To achieve this, the WHO has been assisting its member countries in the formulation and implementation of national drug policies in order to reduce morbidity and mortality from common illnesses by promoting the availability and accessibility to essential medicines. For achieving this goal, a major thrust has been placed on four

access links, namely - Rational use, Affordable price, Sustainable financing and reliable health and supply systems.

2. In view of the ever developing sophistication, modernization, automation and upgradation of manufacturing technologies competing environment, an efficient procurement system is the only way to improve access to medicines for the majority of the population within the given budgetary ceilings. Since availability of financial resources is always a constraint for developing countries, it becomes all the more important to improve efficiency in all aspects of management in the countries. Finally, good procurement is a linchpin of access to quality and appropriate medicines.
3. The WHO, in partnership with UNICEF, United Nations Population Fund (UNFPA) and the World Bank, has drawn on a common bank of extensive experience to produce “Operational Principles for Good Pharmaceutical Procurement”, to assist all those involved in procurement to obtain lower prices, better quality and more reliable delivery of essential medicines, based on four strategic objectives.
4. This project has reviewed the drug procurement systems in the states of Delhi, Tamilnadu, Andhra Pradesh, Orissa and the procurement by the HSCC.
5. **“Delhi Model” of Drug Procurement:** Before the introduction of this system of procurement, each hospital in Delhi used to procure the drugs independently. The system was ruined by mismanagement and corruption. Many of the drugs so procured by the hospitals were rarely needed while the required medicines were almost perennially in short supply.
6. The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is a non-profit organization which has introduced the centralized drug procurement system with the government hospitals of Delhi in 1996 with the technical support of the WHO. The objective of the “Delhi model” of drug procurement was to ensure availability of good quality medicines with these hospitals and to promote rational drug use.
7. Under the initiative, it was found that only a limited number of basic drugs were actually needed for treatment in almost 90 per cent of the hospital cases. These were identified and procured centrally for supply to the hospitals.
8. The pooled procurement system uses a two-stage tender system, which ensures that only those companies that are capable of supplying products of adequate quality receive orders. Through a **two-envelope system** (technical bid and price bid), the drug purchase committee of the DSPRUUD is able to ensure that the purchases are made from GMP compliant-companies. The companies are required to undergo GMP inspections and random testing of products. The doctors are asked to prescribe only products on the procurement list, although hospitals are allowed to use up to 10% of their drug budget on unlisted products.
9. The pooled procurement system is now in place for all state-run hospitals and 150 primary health centers in Delhi. The pooled procurement system has resulted in a fall in drug prices to the hospitals by 30-40%, better quality assurance and less duplication of effort. About 80% of the patients in the hospitals run by Delhi Government are now supplied all prescription drugs.

10. A list of 250 essential drugs was prepared for larger hospitals and a list of 100 for smaller hospitals. The list is revised from time to time. The hospitals in Delhi now spend over 90% of their drug purchase budget to buy these listed medicines.
11. **Tamil Nadu Model:** A Govt Company, Tamil Nadu Medical Service Corporation (TNMSC), has been estd in 1995 with the primary objective of ensuring ready availability of all essential drugs and medicines in all the government health facilities by adopting a streamlined procedure for their procurement, storage and distribution.
12. As a first step, TNMSC finalised the list of essential drugs to be procured. Keeping in view the WHO's Model List of Essential Drugs, the then existing list of nearly 900 drugs was pruned to a list of 240 drugs. Now, TNMSC has 271 items of drugs and medicines that account for around 90% of the budget outlay for the purpose.
13. In order to ensure the procurement of only quality drugs at competitive prices, an **open tender system** is followed and purchases are made only from GMP-certified manufacturers with a market standing for at least 3 years. To eliminate sole dependence on one supplier, the next two suppliers willing to match the lowest price are also approved.
14. With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practice of bulk packing which required manual handling at the time of distribution. Both inner and outer packages of all items bear the logo of TNMSC to show that the drugs are manufactured only for the state government supply and are Not for Sale. On account of this, the credibility and acceptability of the drugs by the public also improved immensely.
15. For effective quality control, samples drawn from different batches are coded and sent to private approved laboratories to ensure effective quality control.
16. In order to ensure a **regular supply** and for preventing stock-outs, TNMSC has established a chain of godowns and the suppliers are required to supply the drugs to the district warehouses, which would keep a working stock of three months requirement at any point of time. Each institution is given a passbook indicating its annual entitlement (i.e. budgetary allocation) within which it can draw drugs from the district warehouse.
17. TNMSC works on fully computerised systems in all aspects. Each district warehouse is linked to the Head Office via the Internet. As the receipt and issue of drugs at all the district warehouses level is done using computers, the information on the inventory level for any drug at any warehouse at any point of time is readily available with the Head Office, on the basis of which the stock position is effectively monitored and re-order is effected to prevent any stock out situation.
18. Impact of the new system: Improved availability of drugs in nearly 2000 government medical institutions throughout the State, savings in the outlay on drugs to the extent of 36% of the allocation, better budgetary control on drug consumption, medical institutions becoming more cost conscious and a better perception in people in addition to **enhanced availability** of drugs at all facilities are some of the important points as far as the impact of the new system is concerned.
19. Drug Procurement in Andhra Pradesh: The public health care system of AP comprises of three levels of service delivery and finance, viz. primary, secondary and tertiary

- care. The nodal agency for purchase of drugs in the state is the “Drug Procurement Wing” of the Andhra Pradesh Infrastructure State Development Corporation (APISDC).
20. In Sept 1998, a centralized pooled procurement system was initiated. Accordingly, only those suppliers who had a stake in their long term reputation, and adopted good manufacturing and trade practices, were allowed to participate in the tender system, i.e. a technical bid was introduced before the actual financial bid.
  21. The two-part system of bidding and procurement has considerably improved the supply and quality of drugs, and successfully discouraged the practice adopted earlier by certain firms of quoting unreasonably low rates in their bids to be included in the rate contract and then making up by short supplying and compromising on quality. A notified committee draws the selected list for procurement and rate contracts are finalized on the selected list of drugs centrally by another notified committee. Indents are collected from hospitals and consolidated by the nodal agency and orders are placed before the firm to make the delivery to the medical stores in each district with the **advantages** that the drugs when purchased in bulk may be bought for a lower price directly from the manufacturers, transportation of these drugs is borne by the supplying firm and loss/theft during transport is the responsibility of the firm.
  22. A Primary Health Centre (PHC) can draw only 43 listed items. The superintendents of district hospitals have 10% of the allotted funds at their disposal for purchase of emergency medicines and the Superintendents of tertiary hospitals have 20% of the allotted funds at their discretion for similar purpose. Quality controls are regularly conducted.
  23. This experience reflects that an autonomous organisation with a supportive board can perform very well and approve the rates of procurement of drugs centrally, availing the advantage of bulk/pooled procurement, yet effect the deliveries of supplies in decentralised district drug stores, the cost of which is borne by the supplier. A single window system for all inputs, processes and outcomes can work effectively with a fairly close monitoring of flow of funds etc.

This review, alongwith the questions posed by the participants, points to following issues:

- a) There are strong models of drug procurement within the country and they continue to work well.
- b) However, it has *never been quantified* that how many individuals are actually able to draw the benefit of this revised procurement. An assessment, through a study, would be meaningful to explore this.
- c) The *quality assurance of the procurement process* has not been discussed. For a model to remain in practice, it is imperative that the processes be validated through an appropriate tool.
- d) Preferential or protectionism clause in favour of certain categories of industries (like SSI) may discourage many prospective quality manufacturers to stay away from the competitive bidding process.

#### Technical Session 4

Mrs.Prabha Garg gave an overview of the mechanisms for pricing of drugs not only in India, but several other countries also.

- Drugs Price Control in India was discussed. Four DPCOs 1970, 1979, 1987 and 1995 were presented with number of drugs under price control, categories and their market share.
- The objectives of current DPCO i.e. DPCO 1995 was also discussed. To fix/ revise the prices of controlled bulk drugs and formulations and to enforce the implementation of the DPCO 95, NPPA was established. Mandate & functions of NPPA was also discussed.
- The methodology for fixation of prices in India for schedule bulk drugs and their formulations was discussed.
- Implications of Drug Price Control and Decontrol with respect to profit, investment, production and export of bulk drugs and formulations and expenditure on R&D in Indian pharmaceutical industry were discussed.
- Also discussed the drugs pricing mechanisms in other countries like Australia, Brazil, Canada, France, Germany, Greece, Japan, Republic of Korea, Mexico, Poland and Switzerland.

#### Following inputs and suggestions came up during the presentations:

**Q.1** *Mr.Nandraj, WHO representative, New Delhi addressed to Dr.Parikshit Bansal.*

" The results of the study are based on ten years data compiled from Indian Drug Review ie. secondary source of data. The same needs to be mentioned in the report and included under the head "limitations of the study".

**Ans. Dr.Parikshit Bansal:** The data source had already been indicated in the table given. A separate heading on limitations can be included in the final report.

**Q.2.** *Mr.Sakthivel, Instt. For Human Development, New Delhi, addressed to Dr.P.Bansal).* It needs to be clarified whether the prices are wholesale prices or retail prices and whether any normalization has been done. Also, details of packing need to be specified.

**Ans. Dr.Parikshit Bansal**

- The prices given are NOT wholesale prices of the drugs, but retail prices ie. prices at which the drugs were actually available to consumers. No normalization ie. consideration of inflation etc. was taken into account. Even in the absence of normalization, the prices are showing a stable and in some cases a downward trend, over a ten year period. If the inflation factor is also included, then the 'prices' in real terms will show a further fall, rather than increase. The same was agreed to by the enquirer.
- Regarding packing, the same has already been mentioned for each therapeutic category, (packing size, tablet weight) in the table.

**Q.3.** *Mr.Sakthivel, Instt. For human development, addressed to Mrs. Prabha Garg and Dr.P.Tiwari*). The trends in data regarding fall in profitability is not correct. Raw Data source needs to be cross-checked. Also, in none of the tables, data source is mentioned. If taken from any website, the same must be cited. Mechanisms of pricing for different countries as presented, must indicate data source.

Similarly, even in drug procurement mechanisms, source of information must be cited.

**Ans. Mrs.Prabha Garg**

The data can be cross-checked. Data sources will be mentioned and included in the final report.

**Dr.Pramil Tiwari**

Data on drug procurement mechanisms has been collected from available public resources. The same will be cited in the final report.

### **GENERAL COMMENTS FROM THE AUDIENCE**

1. Overall, the methodology used and the trends obtained are distinct and easily understandable.
2. Study can be extrapolated further and in fact should be continued by NIPER to keep a watch on prices.
3. While granting patents, patent office should also concur with the drug controller and Ministry of Chemicals and Fertilizers regarding pricing.

### **RESPONSE BY MR.RAJESH BHUSHAN, DIRECTOR, MOHFW,**

- Regarding involvement by Controller of Patents, of Drug Controller and Ministry of Chemicals and Fertilizers, when granting patents, the same is an open suggestion. It needs debate and discussion. Moreover, major policy level decisions are involved.
- Mr.Rajesh Bhushan expressed his overall satisfaction with the report and expressed a desire for further such studies by NIPER.

### **GENERAL COMMENTS BY DR. NARESH KUMAR, HEAD, RDPD, CSIR HQ, NEW DELHI**

- Dr.Naresh while giving an overview of the TRIPS agreement had indicated that there were considerable fears and misgivings amongst the general public, regarding patents and drug prices.
- The TRIPS agreement and subsequent discussions during the DOHA round had attempted to address these concerns by duly including provisions in which if there was a conflict between public welfare and patents, public welfare would get priority. Considerable flexibility was given to the signatory countries in framing their own laws and guidelines to safeguard public interest.
- Moreover, the pricing of drugs was a multi-faceted phenomenon, not dependent on a single factor such as patents alone.
- The NIPER study in which 10 years data on drugs in various therapeutic categories had been compiled, showed a stability in prices of drugs in most cases and even fall in prices in some cases after TRIPS.

- This indicated that drug pricing was a multifaceted phenomenon.
- Dr.Naresh cautioned that the present study was confined to generic drugs only and the real affect of product patents on prices of patented drugs could only be determined 4-5 years from now.
- At this stage it was difficult to predict how prices of patented drugs would be affected in the future.
- However, it is a fact that at any period of time, generic drugs would dominate the market. It was clear from the NIPER study that prices of generic drugs were not showing an increase and were rather falling in some cases.

### **CONCLUDING REMARKS BY DR. P. RAMA RAO**

- Dr. Rao in his concluding remarks stressed the need for a reassessment of the drug pricing mechanisms. Moreover, he indicated that drug pricing was a multifaceted phenomenon, not dependent on patents alone.
- A number of factors e.g. taxation structure, liberalization measures, inflation rate, technological competence etc. came into play when it came to drug pricing.
- There was a need for monitoring the prices of drugs on the National List of Essential Medicines on a regular basis. This could be done by setting up a website in which free access to the information was available.
- Also, there was a need for validation of the procurement and purchase procedures, not only at state but at national level. Successful models of drug procurement e.g Tamil Nadu Model need to be replicated.
- Regarding pricing of patented drugs, Dr.Rao clarified that globally every year around 20 new patented drugs enter the market, while the total number of drugs is approximately 700. Hence, patented drugs constitute a minority (nearly 3% of total).
- Generics command a very significant share of the market and their prices are not affected by patents. In fact, generic drugs are 'off-patent' drugs, which can be freely manufactured by any manufacturer, since patent restrictions are no longer there.

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**Comments communicated vide email by Mr.Sakthivel, Instt. For Human Development, New Delhi, addressed to the investigators of this project. (after the TRIPS dissemination workshop held at NIPER, on 22nd April, 2006)**

Dr. Bansal,

I would like to place the following comments on your study:

1. The assertion made in Page 37, using fig. 3.1. that profitability trend (PBT) had taken a beating during late 1980s and early 1990s due to price control needs a rethink. This is due to factual inconsistency in the argument as well as fallacy in causes attributed. As far as factual inconsistency is concerned, profitability trend measured by Profit Before Tax (PBT), Profit After Tax (PAT), etc.. The Ratio of PAT to Net Worth, The Ratio of Dividends to Net Worth, or name it, all the criteria related to pharma industry indicate a rising trend of profitability irrespective of any policy measures. This fact is borne by looking at data sources, such as, RBI/CMIE-Prowess/Capitaline, etc.. Even assuming that the data quoted in your is reliable, the fallacy of the argument lies in the fact that profitability started rise since the early 1990s while DPCO, 1995 was initiated only in 1995.
2. Another aspect that got my attention while going through your report is in page 39 and 40 using fig 3.4 asserts that price control and decontrol is responsible for the low R&D expenditure and later rising R&D expenditure respectively. If you deflate the expenditure and take a look at it, you would arrive at a different picture. This is due to the fact that late 1980s and till about mid-1990s, inflation at its peak in recent years of over two-digit while the same has hovered less than eight percent in the late 1990s. Moreover, price control and R&D expenditure do not have any correlation, rather it is to do with the success of few top-end companies having tasted success in generic market in the developed economies. In addition, it may also be noted that only a handful of companies account for the major chunk of R&D expenditure in recent years in India and a phenomenal share of it goes into generic products of off-patented drugs rather than on blockbuster New Chemical Entities (NCE).
3. As regards the chapter on drug procurement system is concerned, does your report has any data to validate your conclusion? Or else it will remain to be merely a literature review. If the question it to replicate either Delhi Model, TNMSC Model, AP Model or Orissa Model in terms of cost saving, efficacy, etc.. and its relevance to public health care institutions, there is a need to study it in detail with data drawn from different sources.
4. In your model (can it be called a model?), there was a mention about why global level selection of major therapeutic categories was not undertaken while categories were picked up from Nagesh Kumar and Watal' study. I think that since NIPER has the facility of access ORG-IMS data, it would be better to use ORG-IMS data on top 300 medicines turnover, which captures well over half of India's market.

5. The methodology in page 80 needs further clarification in terms of units, pack size, number of formulations considered, etc.. This needs to be clearly spelt out in running text rather than in tables.
6. Another interesting aspect that I note in Page 94 is about your model testing. There is a comparison of India and Pakistan. It is an established fact that India's technological capacity lies in reverse engineering attributed solely to process patent regime while that of Pakistan's low technological capacity is to do with product patent regime that stifled the growth of indigenous pharma industry, given similar socio-economic conditions prevailing in both the countries. India's success story of high (?) technological capacity did not come from vacuum but from a pro-active state policy (process patent regime).

#### **Clarifications on point no.s 1 & 2 (by Mrs.Prabha Garg)**

**Point 1:** The assertion made is correct. The profitability trend is expressed as ' % of sales' and not ' net profits'. DPCO resulted in reduced profits as a '% of sales' and not a 'net reduction in profits'. The industry would not have been able to operate if profits nosedived. The diagram under question has been cited in the article by Piyush Kunnopalil (copy enclosed) and is based on statistics obtained from the website of OPPI cited at [www.indianoppi.com/profitable chart.htm](http://www.indianoppi.com/profitable chart.htm)

**Point 2:** The observations are well-made.

#### **Clarifications on point no. 3 (by Dr. P. Tiwari)**

**Point 3:** The terms of reference of this study required a review of the procurement mechanisms in the public health sector, which has been duly carried out. The review has highlighted the benefits of each innovative procurement model in which the benefits, in terms of actual financial savings on drug budget, have been duly quantitated and expressed in the report.

#### **Clarifications on point nos. 4, 5 and 6 (by Dr. Parikshit Bansal)**

**Point 4:** This study is by no means an end. It has yielded very interesting data and further work as proposed can be carried out as a separate project. Existing work as documented had been duly approved by competent authority.

**Point 5:** The suggestion is well-made and appropriate inputs as suggested have been duly incorporated in the final report.

**Point 6:** It is true that there is a wide variation of prices in Pakistan and India. Product patents alone cannot be blamed for this discrepancy, since the drugs for which prices are higher are generics viz. off-patent. Though it can be assumed that existence of 'product patents' stifled growth of industry, it does not appear to be a very sound assumption, because the generics at any point of time command a major chunk of the pharma segment, be it in India or Pakistan. Since manufacture of generics does not involve any patent issues, why should industry get 'stifled?'.

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# 11. Drudgery of Drug Price Controls: Who Benefits?

Piyush Kunnappallil

## Introduction

The drug prices in India are controlled under the Drugs (Prices Control) Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955<sup>1</sup> empowering it to fix and regulate the prices of essential bulk drugs<sup>2</sup> and their formulations<sup>3</sup>. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

In this paper, I seek to examine the nature of deregulation of drug prices that has occurred in India over time and the impact of the same on the pharmaceutical industry.

## Control and Decontrol of Drug Prices—A Historical Account

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. Individual as well as comparative analysis of all the DPCOs illustrates that there has been a measured but sturdy decontrol of drug prices in India. This analysis has been presented below.

### 1947-1970

At the time of independence, the bulk drug industry in India was in the infancy stage with a meager investment of Rs ten crore and a production worth just Rs 26 crore. Most of the bulk drugs and formulations were imported.<sup>4</sup> Till 1962, the drug industry was bereft of any price control. In 1962, there was Chinese aggression on India and Emergency was declared. The government feared that, as a result, drug prices might rise. Accordingly, for the first time, under the Defense of India Act, 1915, statutory control was imposed on the prices of drugs and pharmaceuticals. The Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963 were promulgated. Under the Drugs Prices (Display and Control) Order of 1966, it was made obligatory for the manufacturers to obtain prior approval from the government before increasing the prices of any formulation.<sup>5</sup>

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<sup>1</sup> The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central Government. The Act defines "Essential Commodities" to include drugs since they are considered essential for the health of society. Section 3 of the Act authorises the Central Government to regulate or prohibit the production, supply, distribution, trade and commerce in any of the "essential commodities" if the same is necessary for maintaining or increasing supplies of these commodities for securing their equitable distribution and availability at fair prices. (Source: The Essential Commodities Act of 1955)

<sup>2</sup> A bulk drug is any pharmaceutical, chemical or biological product including its salts, esters, stereoisomers and derivatives, conforming to pharmacopoeia or other standards and which is used as such or as an ingredient in a formulation. (Source: The Drugs Prices Control Order, 1995)

<sup>3</sup> A formulation is a medicine processed out of bulk drug/s for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any medicine included in the Ayurvedic, Homeopathic or Unani system of medicines. Hence, the DPCO is applicable only to allopathic drugs. (Source: The Drugs Prices Control Order, 1995)

<sup>4</sup> This particular statistic was obtained from the website of The Bulk Drug Manufacturers Association accessed at <http://www.bdm-assn.org/aboutus.html>.

<sup>5</sup> "History of Drugs Price Control," *Role of NPPA in Drug Pricing*, published by National Pharmaceutical Pricing Authority.

### DPCO, 1970

On 16 May 1970, a comprehensive order was promulgated under Section 3 of the Essential Commodities Act and in supersession of all the earlier orders on the subject. This order was called the Drugs (Prices Control) Order, 1970.<sup>6</sup> In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. The government stipulated that a company's pre-tax profit from its pharma business should not exceed 15% of its pharma sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the government. So, a pharma company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the government, bureaucratic hurdles were low. At that time, the Indian pharmaceutical industry was largely dominated by MNC affiliates and subsidiaries. These MNCs were hardly affected by the relatively mild form of DPCO and continued operating in the domestic market. However, FERA (Foreign Exchange Regulations Act) which came in mid 70s did curb the operations of MNCs. Overall, the Indian pharma industry prospered from 1970 to the next DPCO in 1979.<sup>7</sup>

### The Hathi Committee, 1974

In 1974, the GoI appointed a committee under the chairmanship of Rajya Sabha MP Jaisukhlal Hathi to enquire into the conditions prevailing in the sphere of pharmaceuticals in the country. The committee submitted its report in 1975, which is widely known as the Hathi Committee report. The report strongly emphasised greater role for the public sector in the manufacturing of drugs. The DPCO, 1979 was loosely based on the recommendations of the Hathi committee but many a provision were not implemented.<sup>8</sup>

### DPCO, 1979

The Drugs Prices Control Order of 1979 was issued on March 31.<sup>9</sup> In its revised version, the DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. In fixing the price, the government continued to advocate the profitability ceiling and an upper limit was put on the return on net worth or capital employed for pharma companies. The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post manufacturing Expenses). It was a mark-up on ex-factory costs, provided to cover selling and distribution costs including retail and wholesale trade margins.

The pricing formula was retail price<sup>10</sup> = (MC+CC+PM+PC) x (1+MAPE/100) + excise duty, where MC was the material cost including cost of bulk drugs/excipients, CC was the conversion cost as per the dosage form is, PM was the cost of packing material suitable to dosage form and PC was the packaging charge worked out in accordance with established costing procedures. The DPCO, 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPE. See the table below. The most important drugs, including life saving drugs were put in Category I which had the least MAPE.

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<sup>6</sup> "History of Drugs Price Control" *Role of NPPA in Drug Pricing*, National Pharmaceutical Pricing Authority.

<sup>7</sup> "Drug Price Control Order (DPCO)" *Pharmaceutical Industry*, India Info line Limited.

<sup>8</sup> This section is based on my conversation with Arya of Indian Drug Manufacturers Association.

<sup>9</sup> "History of Drugs Price Control" *Role of NPPA in Drug Pricing*, National Pharmaceutical Pricing Authority.

<sup>10</sup> This was not the Maximum Retail Price (MRP) of the formulation. Local Taxes were added at the time of sale.

Category	MAPE
I	40%
II	55%
III	100%
IV	60%

Through this DPCO, around 80% of the Indian pharma industry (in value terms) was brought under strict price control. The MNCs were the worst hit. With profitability falling steeply, they discontinued many products, especially the life saving products in Category I. In addition, the industrial licensing requirements made it impossible for MNCs to introduce new products. The local players were, nonetheless, in a better position. They could obtain licenses much easily than MNCs could. They were also able to speedily introduce new drugs. The local players, as a result, were able to keep the coverage of DPCO low and fight the might of established MNCs. However, profitability wise, the Indian pharma sector went through its worst phase from 1979 to 1987.<sup>11</sup>

#### The Kelkar Committee, 1984

In 1984, the Kelkar Committee came out with its report in which it recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. The committee stressed the need to liberalise the strict profitability curbs that were acting as a hurdle to the growth of the pharma sector.<sup>12</sup>

#### DPCO, 1987

The DPCO, 1987 was promulgated on August 26 on the basis of the Drug Policy of 1986 and the Kelkar Committee Report. In the DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 370 to 142. 20 drugs were taken off from Category I and 122 from Category II.<sup>13</sup> In addition, the categories of control were reduced to two and higher MAPE was provided for each category of controlled drugs. See the table below. The MAPE for Category I and Category II was increased from 40% and 55% respectively to 75%. The MAPE for Category IV was increased from 60% to 100%. Even the new drugs that were brought under price control got a liberal 75% MAPE.

Category	MAPE
I	75%
II	100%

Furthermore, industrial licensing norms were made softer thereby improving the situation of MNCs desirous of amending their product mix. As a result of all these factors, profitability improved. However, around 75% of the pharma industry was still under price control.<sup>14</sup>

<sup>11</sup> "Drug Price Control Order (DPCO)" *Pharmaceutical Industry*, India Info line Limited.

<sup>12</sup> This section is based on my conversation with Arya of Indian Drug Manufacturers Association.

<sup>13</sup> "History of Drugs Price Control" *Role of NPPA in Drug Pricing*, National Pharmaceutical Pricing Authority.

<sup>14</sup> "Drug Price Control Order (DPCO)" *Pharmaceutical Industry*, India Info line Limited.

### The Drug Policy of 1994

In September 1994, the new drug policy was announced. It is the Drug Policy of the government that decides the criteria for selecting bulk drugs or formulations for price control. The New Drug Policy liberalised these criteria. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed and it was expected that, as a result, supply would rise resulting in higher competitive pressures. Foreign investment up to 51% was also permitted in case of all bulk drugs, their intermediates and formulations. FDI above 51% was to be considered on a case to case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxytetracycline were reserved for the public sector till 1998.<sup>15</sup>

### DPCO, 1995

The latest Drug Price Control Order was passed on 6 January, 1995. The basic structure of this DPCO is the same as that of the earlier two orders. Nevertheless, the span of price control under DPCO 1995 has been liberalised considerably from 142 drugs to just 76.<sup>16</sup>

*The Pricing of Bulk Drugs:* The 76 bulk drugs, the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. The methodology through which prices of DPCO-controlled bulk drugs are fixed is as follows. While fixing the maximum sale price of a bulk drug, the government has to provide either a post-tax return of 14% on net worth or a return of 22% on capital employed.<sup>17</sup> Each company can choose one of the two methods mentioned above as per its own free will. So, the choice of method is company-specific and not product-specific. Then based on the chosen method, each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved. The government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers, before arriving at the final price. The price so decided will be binding on all manufacturers, irrespective of their actual cost of production.

*The Pricing of Formulations:* The Drug Price Control Order covers all the formulations that utilise the bulk drugs listed in the First Schedule. The methodology through which prices of formulations are fixed is as follows. Under DPCO 1995, a uniform MAPE of 100% is given on all formulations under price control. This is in contrast to the earlier practice of giving a MAPE of 75% on some formulations. In the new system, the retail price of a DPCO formulation is fixed equal to  $(MC+CC+PM+PC) \times 2 + \text{excise duty}$ . It is this price that is printed on the pack of a DPCO-controlled formulation. This price is not the Maximum Retail Price (MRP). Local taxes are additional. In order for the government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the government details of material cost, manufacturing process etc. The ceiling prices, once decided, are notified in the Official Gazette. For imported drugs and formulations, the landed cost including customs duty and clearing charges is the benchmark to fix prices. The margin allowed to the importer is such that selling and distribution expenses including interest and profit are covered. However, the margin allowed cannot exceed 50% of the landed cost.

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<sup>15</sup> "Drug Price Control Order (DPCO)" *Pharmaceutical Industry*, India Info line Limited.

<sup>16</sup> This section is largely based on the information gathered from the following book: "Drug Price Control Order (DPCO)" *Pharmaceutical Industry*, India Info line Limited.

<sup>17</sup> In respect of a new plant, an IRR of 12% based on long-term marginal costing is allowed and where production is from basic stage, a post-tax return of 18% on net worth or a return of 26% on capital employed is allowed.

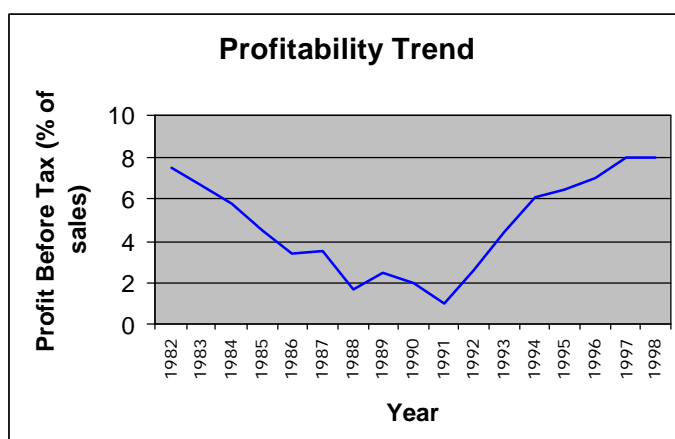
## Implications of Drug Price Control and Decontrol for the Pharma Industry

The impact of drug price control and decontrol on the Indian pharmaceutical industry can be analysed on the following three fronts.

### Profitability

Of all the parameters that can be used to judge the impact of drug price control and decontrol on the pharma industry, the parameter of profitability is the most important. Consider Exhibit 1.

Exhibit 1

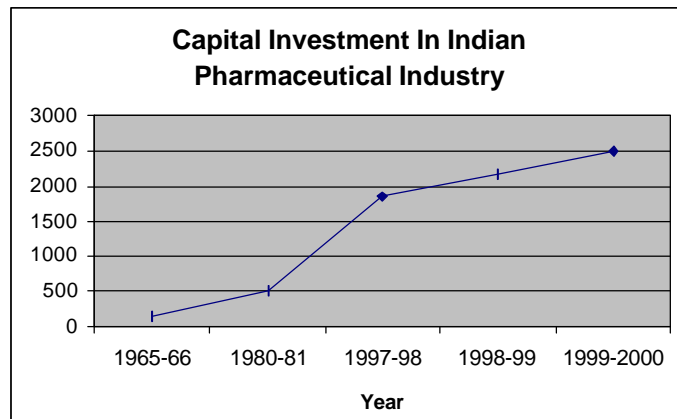


The diagram<sup>18</sup> depicts the profit before tax (as % of sales) for the Indian pharma industry for the period 1982-1998. The illustration is unique in that we get an unambiguous “V-shaped” graph. It is obvious from the graph that the profits of the pharma industry plummeted over the period 1982-1991 and thereafter registered a stupendous increase. The control and decontrol of drug prices played an important role in this trend.

Till 1987, 90% of all drugs produced in India were controlled as regards their prices. This put severe strain on the profit margin of the industry. There might have been other factors as well but drug price control was certainly a major factor responsible for the decline in industry profits in the pre-1990 period. The post-1987 period saw the DPCO being revised twice—first in 1987 and then in 1995. In the first revision, price control on drugs was eased and made applicable to 65% of all drugs as opposed to 90% earlier. In the second revision, this came down to 40%. With the strain on profit margin being eased, the industry's profits skyrocketed. As the industry became more profitable and viable, capital investment into the Indian pharma Industry increased. See Exhibit 2.

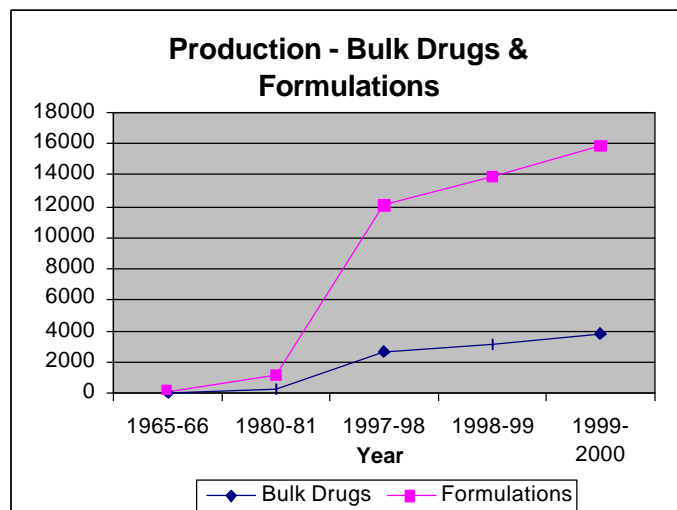
<sup>18</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/profitablechart.htm>. The source of data for different years are the following: the NCAER study for the years 1982 and 1983, A F Ferguson's Study for the year 1984, OPPI's Estimate for the years 1985 and 1986, OPPI's Surveys for the years 1987, 1988, 1989, 1990, 1991, 1992, 1993 and 1994, and OPPI's Estimate for the years 1995, 1996, 1997 and 1998.

Exhibit 2



Consider Exhibit 3. The diagram depicts the production of bulk drugs and formulations by the Indian Pharmaceutical Industry over the period 1965-2000. It is clear from the graph that the manufacture of drugs and formulations in India for the first 15 years was measly and it was only in the last decade that the industry picked up in terms of production capacity.

Manufacturing  
Exhibit 3



Again, drug price control and decontrol was a major feature in this trend.

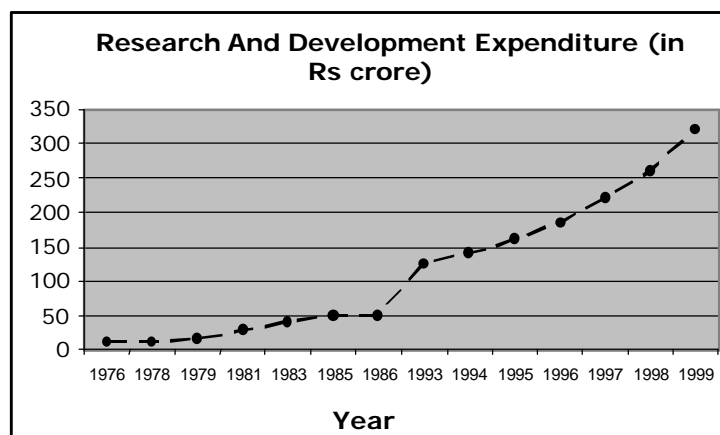
In the Drug Price Control Order, 1979, which stayed enforced till 1987, 90% of all drugs were under strict price control. With such massive regulation on the prices of most drugs and thereby on the profitability of the manufacturing companies, the production of scheduled drugs became unfeasible. For instance, no export orders were taken on controlled drugs since their supply had to be under certain parameters. As a result, the level of manufacture by the pharma industry declined.

In the DPCO, 1987 and then in the DPCO, 1995, the proportion of drugs under price control declined to 65% and to 40% respectively. With a large number of drugs being taken out of price control, the production of these drugs became feasible again. As a result, the manufacture of these drugs increased.

Consider Exhibit 4.<sup>19</sup>

### Research and Development (R&D)

Exhibit 4



The diagram illustrates the expenditure on research and development incurred by the Indian Pharmaceutical Industry over the period 1965–2000. It is patent from the diagram that for the first 15 years, expenditure on R&D was almost stagnant and it was only in the 1990s that expenditure on this front really picked up. The control and decontrol of drug prices is a major explanatory factor of this trend.

Until around the 1990s, the drug prices were strictly controlled. This stifled expenditure on R&D in more ways than one. First of all, the profit margin of the industry came down. With an inadequate profit margin, the industry never ventured out in the field of R&D. Second, it dissuaded foreign players and MNCs from entering the market. In fact, the share of foreign companies in the domestic drug market has continuously declined. See Exhibit 5.<sup>20</sup> Also, the imports and exports were meager. See Exhibit 6.<sup>21</sup> With the local players hardly getting any competition from foreign drug manufacturers, they never felt the need of investment in R&D. There were also reasons other than the control of drug prices for the slack R&D expenditure. For instance, process patents had been granted to the industry under the Indian Patent Act of 1970 and the domestic manufacturers simply had to reverse engineer<sup>22</sup> drugs made abroad. They were able to foray into various therapeutic segments and there was no need to indulge in any R&D.

<sup>19</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/researchchart.htm>.

<sup>20</sup> This diagram is based on the statistics obtained from "Indian Pharmaceutical Industry--Issues And Options" published by FICCI.

<sup>21</sup> This diagram is based on the statistics obtained from the website of the Organization of Pharmaceutical Producers of India cited at <http://www.indiaoppi.com/importcompchart.htm> and <http://www.indiaoppi.com/exportschart.htm>.

<sup>22</sup> Reverse engineering effectively implies pirating somebody else's technology by dismantling an existing product, and reproducing its parts and construction to manufacture a replica.

Exhibit 5

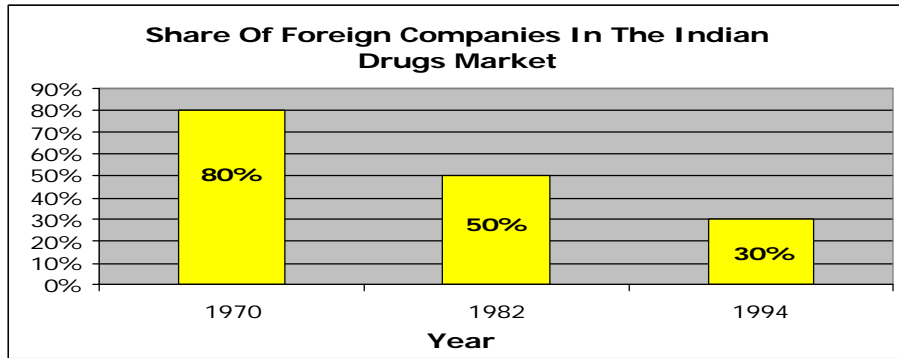
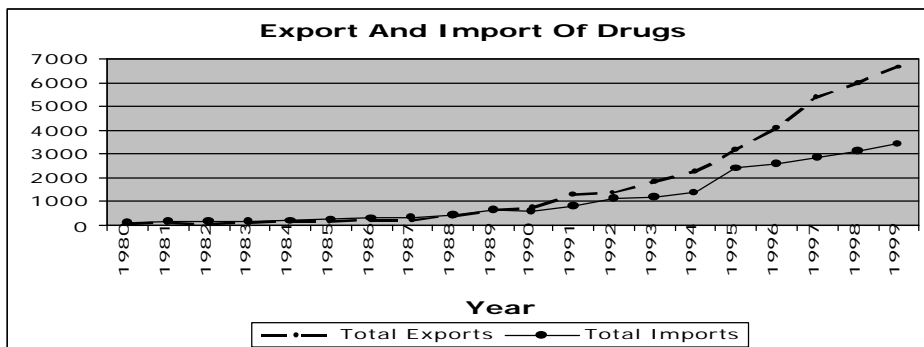


Exhibit 6



However, things changed in the 1990s, when controls on drug prices were eased. First of all, profit margin for the domestic drug manufacturers increased thereby enabling local players to provide for R&D. Second, foreign trade in drugs increased (see Exhibit 3) thereby raising the level of competition in the domestic and international market and necessitating greater R&D. However, there were factors other than the decontrol of drug prices, which propelled R&D. For instance, under the TRIPS agreement, process patents were replaced with product patents. This shut the door on reverse engineering and made expenditure on R&D an inevitability for the local players.

### Conclusion

It is patently clear from the historical analysis that successive Indian governments have steadily decontrolled drug prices in India. In the last 14 years, the degree of drug price regulation has dipped by 50%. As far as the speed of deregulation of drug prices is concerned, it is a matter of debate.

It is also clear from the above discussion that the Indian pharmaceutical industry has heavily benefited from deregulation. Not only has the drug market in India become more profitable and viable, the production capacity and the research and development expenditure of Indian companies has also witnessed a significant increase.

This paper, however, remains deficient in one respect. It does not analyse the impact of deregulation of drug prices on the Indian consumer. My efforts in this regard have been unsuccessful largely due to the difficulty involved in collecting and compiling data on inter-temporal prices, accessibility and quality of drugs. Only a comprehensive and discreet investigation into this particular aspect will reveal the true nature of the impact of drug price deregulation.