

中国制剂药物市场：现状与前景

Outlook of China Drug Formulation Market



Table of Contents

Scope of the Report	2
About Author	3
Executive Summary	13
<ul style="list-style-type: none"> ◆ Current State of Drug Formulation in China ◆ Roles of Multinational Drug Companies in Chinese Drug Formulation Industry ◆ Comparison of Drug Formulation Industry between China and India ◆ Future Outlook of Drug Formulation in China 	
Chapter One – Current State of Drug Formulation in China	22
Summary	23
1.1. Drug formulation plays increasingly important roles in pharmaceutical industry	25
1.1.1 Areas in which formulation plays key roles	26
1.1.2 Factors affecting drug formulation	27
1. API properties	27
2. How to overcome low solubility and bioavailability	28
1.2. China – Currently strong in API but weak in drug formulation	30
1.3. Analysis of current state of Chinese API industry	31
1.4. Analysis of current state of drug formulation in China	37
1.4.1 Current formulation capability of Chinese drug companies	38
1.4.2 Chinese companies possessing FDA/EMA certified manufacturing facilities for dosage form drugs	42
1.5. Product quality regulation in China: Current state of Chinese cGMP	46
1.6. Key and fast rising players in Chinese drug formulation industry	47
1.7. Current state of contract formulation service of finished drugs in China	50
1.8. Current market size of finished drugs in China	57
1.8.1 Total output of Chinese pharmaceutical industry	57
1.8.2 Current market value of finished small molecule drugs in China	58
1.8.3 How to compare with global finished drug markets	59
1.8.4 Current market value of OTC drugs in China	59
1.9. Current market size of Chinese-made finished drugs marketed overseas	61
1.9.1 Distributions of Chinese-made dosage form drugs marketed in global market	61
1.9.2 Current market values of Chinese-made dosage form drugs marketed overseas	64
1.9.3 Growth history of the market value of Chinese-made finished drugs marketed overseas	66
1.9.4 Key players of marketing finished drugs in international market	68

Chapter Two – Roles of Multinational Drug Companies in Chinese Drug Formulation Industry ----- 70

Summary -----	71
2.1 Introduction -----	73
2.2 Challenges facing global drug companies -----	74
2.3 Multinational drug companies focusing more on emerging markets -----	76
2.4 Multinational drug companies licensing generic drugs from drug companies in emerging countries -----	80
2.5 China has become the major focus of all multinational drug companies among all emerging markets -----	81
2.6 Drug formulation capability and capacity of major pharma companies in China --	82
2.7 Roles of multinational drug companies in Chinese-made finished drugs marketed overseas -----	85
2.8 Multinational drug companies strengthening their manufacturing and marketing capability and capacity in Chinese market -----	89
2.8.1 Overall activities of multinational drug companies in Chinese market --	89
2.8.2 Multinational drug companies strengthening their manufacturing capability and capacity in China -----	91
2.8.3 Multinational drug companies strengthening their marketing capability by launching more new drugs or dramatically expanding their local marketing forces -----	93
1. Increasing sales force in China -----	93
2. Launching more new drugs in Chinese market -----	94
2.8.4 Multinational drug companies acquiring Chinese companies to expand their market space in China -----	95

Chapter Three – Comparison of Drug Formulation Industry between China and India ----- 99

Summary -----	100
3.1 Introduction -----	102
3.2 General comparisons of pharmaceutical industry between China and India -----	103
3.2.1 Comparison of development history of pharmaceutical industry in China and India -----	103
3.2.2 Comparison of pharmaceutical markets between China and India -----	105
1. Chinese pharmaceutical markets -----	105
2. Indian pharmaceutical markets -----	107
3.2.3 Comparison of general capability of pharmaceutical industry between China and India -----	109
1. Chinese pharmaceutical industry -----	109
2. Indian pharmaceutical industry -----	110
3.2.4 Comparison of drug R&D capability between China and India -----	112
3.2.5 Comparison of biotech industry between China and India -----	117
1. Chinese biotech industry -----	117
2. Indian biotech industry -----	118

3.3	Comparisons of API industry and market between China and India -----	121
3.3.1	Export value of Indian-made APIs marketed overseas -----	121
3.3.2	India is China's largest API market -----	122
3.3.3	Indian drug companies marketing formulated drugs around the world but sourcing APIs from China -----	123
3.4	Indian companies' capability in drug formulation -----	125
3.4.1	Export value of Indian-made finished drugs marketed overseas -----	125
3.4.2	India attracting multinational companies to set up divisions for formulation and finished drug manufacturing -----	128
3.4.3	Comparison of contract manufacturing services of finished drugs between China and India -----	130
3.4.4	Top players in the finished drug sector of Indian pharmaceutical industry -----	131
3.5	Analysis of current positions of China and India in the value chain of global pharmaceutical product supply -----	135
3.6	Comparison of cGMP regulations between China and India -----	137
3.6.1	Features of Chinese cGMP regulation -----	137
3.6.2	Features of Indian cGMP regulation -----	138
3.7	Bilateral collaboration between China and India on pharmaceutical industry --	139

Chapter Four – Future Outlook of Drug Formulation in China ----- 141

Summary -----	142
4.1 Introduction -----	144
4.2 Future growth drivers of Chinese drug formulation industry -----	144
4.2.1 External drivers – Favorable environment of global pharmaceutical industry -----	145
1. Global major pharma companies more focusing on generic drugs -	145
2. Major pharma companies' current strategies in pursuing generic drugs -----	146
4.2.2 Emergence of new formulation and drug delivery technologies attracting drug companies around the world -----	148
4.2.3 Internal drivers -----	150
1. Still-fast future growth potential of Chinese pharmaceutical market -----	150
2. China's dual attraction as preferred sourcing destination of APIs and leader of emerging markets for marketing of pharmaceutical products -----	154
3. Attraction of high profit margin of developing finished drugs ----	156
4. Fast growth and improved product quality of Chinese API industry -----	157
5. Government support -----	158
6. More investors interested in Chinese drug companies -----	159
7. Domestic Chinese drug companies increasing their R&D investment in drug delivery and formulation technologies -----	160
4.3 Pipelines of new drugs being developed by Chinese drug companies using new	

delivery technologies -----	162
4.4 Analysis of strategies possibly taken by Chinese drug companies to enter the well regulated market -----	164
4.5 Future development patterns of Chinese drug formulation industry -----	167
4.5.1 More Chinese companies will be able to market their finished drugs in well regulated market -----	168
4.5.2 More consolidations -----	168
4.6 Future development outlook of contract formulation service in China -----	171
4.6.1 Future development outlook of global contract formulation service industry -----	171
4.6.2 Outlook of future development of contract formulation service in China -----	172
4.7 Market growth forecast of Chinese drug formulation industry -----	174
4.7.1 Forecast of market growth of finished drugs in China -----	174
4.7.2 Forecast of market growth of Chinese-made dosage form drugs marketed overseas -----	175
4.7.3 How to compare with the same industry sector of India -----	176
4.8 Obstacles facing Chinese drug formulation industry -----	177
4.8.1 Technical barriers -----	177
4.8.2 Quality control – Analysis of key issues in Chinese cGMP and its difference with the Western standard -----	178
4.8.3 Hurdles to entering well regulated markets -----	180
4.8.4 Fast climbing of living cost in China -----	180
4.8.5 Competition from neighboring countries -----	181

Company Profile ----- 182

List of 21 Chinese Companies That Have Passed FDA/EMEA’s cGMP Inspection of Their Manufacturing Facilities for Dosage Form Drugs -----	183
--	-----

Appendix ----- 228

Appendix I. Research Methodology -----	229
Appendix II. About JZMed, Inc. -----	230

List of Tables

Table 1. Importance of drug formulation -----	29
Table 2. Chinese companies that have FDA/EMEA certified cGMP facilities for API manufacturing (including their contact information) -----	33
Table 3. Examples of Chinese companies improving quality control in their API production -----	37
Table 4. Most common dosage forms Chinese drug companies able to produce -----	39
Table 5. Typical formulation capability of Chinese pharma companies -----	40
Table 6. Growth of the number of Chinese drug companies that have passed FDA/EMEA cGMP certification of their finished drug production -----	

facilities -----	43
Table 7. Chinese companies having passed FDA/EMEA inspection of their production facilities for finished drugs -----	43
Table 8. Chinese CROs/CMOs offering preformulation and formulation services ---	51
Table 9. Chinese CROs/CMOs offering services of protein purification, structural characterization and analytical method development -----	55
Table 10. Growth history of Chinese pharmaceutical industry in terms of its total annual output -----	57
Table 11. Past market development history of the finished Western-style medicines in China -----	58
Table 12. Market growth history of OTC drugs in China -----	60
Table 13. Comparison of growth rates of Chinese OTC drug market and prescription drug market in the past five years -----	60
Table 14. Export values and growth history of Chinese-made finished drugs marketed in South Korea -----	62
Table 15. Change of top five overseas markets in which Chinese-made dosage form drugs are marketed in past four years -----	63
Table 16. Growth of the number of countries where the annual sales market of Chinese-made finished drugs exceeds \$10 M -----	64
Table 17. Current export values of Chinese-made pharma products marketed overseas -----	65
Table 18. Market growth history of Chinese-made finished drugs marketed overseas -----	66
Table 19. Market growth history of Chinese-made biologic products marketed overseas -----	67
Table 20. Change of the numbers of Chinese drug companies having export value of finished drugs exceeding \$1 M in past five years -----	68
Table 21. Blockbuster drugs losing patent protection -----	75
Table 22. Top five major pharma companies in emerging markets (their current sales revenue made from the emerging markets and the proportion in their total global sales revenue) -----	79
Table 23. Market growth history of imported drugs in Chinese market -----	82
Table 24. List of finished drugs marketed by multinational pharma companies in China -----	85
Table 25. Analysis of roles of multinational drug companies in Chinese-made finished drugs marketed overseas -----	86
Table 26. Major pharma companies' 2010 market performance in China -----	87
Table 27. Growth history and forecasted future growth potentials of combined market share of top ten major pharma companies in Chinese pharmaceutical market -----	88
Table 28. Summary of main activities of multinational pharma companies in China --	90
Table 29. Development history, current market size and future growth forecast of the finished Western-style medicines in Chinese pharmaceutical market -----	106
Table 30. Current market sizes of TCMS and biologics in China -----	107
Table 31. Current market value and growth history of Indian pharmaceutical market -----	108

Table 32. Comparison of general capability of pharmaceutical industry between China and India -----	111
Table 33. Drug product development pipelines of some representative Indian pharma companies -----	115
Table 34. Drug product development pipelines of some representative Chinese biotech companies -----	116
Table 35. Comparison of biologic drug market between China and India -----	119
Table 36. Comparison of biotechnology industries between China and India -----	120
Table 37. Growth trend of trade values of pharmaceutical products between China and India -----	123
Table 38. General formulation capability of Indian drug companies -----	126
Table 39. Growth history of export values of Indian-made finished drugs marketed overseas -----	127
Table 40. Top players of Indian drug companies in dosage form drugs and their formulation capability (including contact information) -----	131
Table 41. Growth drivers and resistors of Chinese drug formulation industry -----	145
Table 42. Growth history and forecasted future growth of China's total healthcare spending -----	150
Table 43. Comparison of the ratios of annual healthcare spending to GDP between China and other BRIC countries -----	151
Table 44. Forecasted growth of Chinese pharmaceutical market by 2015 -----	153
Table 45. China standing out as a place of having dual attraction for both pharma products sourcing and marketing -----	154
Table 46. Different value shares of pharma products in total pharmaceutical product supply chain -----	156
Table 47. Chinese drug companies having recently received venture capital investments -----	159
Table 48. Products under development in Chinese drug companies using new drug delivery/formulation techniques -----	162
Table 49. Obstacles Chinese drug companies face to enter well regulated market ---	166
Table 50. Latest examples of consolidations in Chinese pharma industry -----	169
Table 51. Chinese companies able to manufacture high potency drugs -----	173
Table 52. Forecasted growth rates of all sectors of Chinese pharmaceutical industry -----	174
Table 53. Forecasted growth of Chinese-made dosage form drugs marketed overseas -----	175
Table 54. Forecasted growth of Indian-made dosage form drugs marketed overseas -	176

List of Figures

Figure 1. Summary of current state of Chinese API manufacturing industry -----	32
Figure 2. Growth trend of the number of Chinese drug companies possessing FDA/EMA certified manufacturing facilities for dosage form drugs -----	43
Figure 3. Growth trend of total output of Chinese pharmaceutical industry -----	57
Figure 4. Market growth trend of the finished Western-style medicines in China ----	58
Figure 5. Market growth trend of OTC drugs in China -----	60

Figure 6. Comparison of growth trends between OTC drug market and prescription drug market in China -----	61
Figure 7. Market distributions of Chinese-made dosage form drugs marketed overseas -----	62
Figure 8. Growth trend of the number of countries in which the annual sales of Chinese-made finished drugs exceed \$10 M -----	64
Figure 9. Product distributions of Chinese-made finished drugs marketed overseas --	66
Figure 10. Market growth trend of Chinese-made finished drugs marketed overseas -	67
Figure 11. Market growth trend of Chinese-made biologics marketed overseas -----	67
Figure 12. Revenue loss of global pharmaceutical industry due to patent expiry -----	76
Figure 13. Growth trend of top five major pharma companies in emerging markets --	79
Figure 14. Growth trend of imported drugs in Chinese market -----	83
Figure 15. Major pharma companies having manufacturing facilities in China -----	83
Figure 16. Growth trend of combined sales revenue of multinational drug companies marketing their China-made finished drugs in international market -----	86
Figure 17. Current rankings of top ten major pharma companies in Chinese market based on their 2010 China sales revenues -----	87
Figure 18. Growth trend of combined market share of top ten major pharma companies in Chinese market -----	89
Figure 19. Changes of rankings of Chinese pharmaceutical market in global market in past eight years -----	106
Figure 20. Compositions of current Chinese pharmaceutical market -----	107
Figure 21. Changes of rankings of Indian pharmaceutical market in global pharmaceutical market in past eight years -----	108
Figure 22. Growth trend of Indian pharmaceutical market and comparison with its Chinese counterpart -----	109
Figure 23. Comparison of growth trends of biologic drug markets between China and India -----	119
Figure 24. Market growth trend of Indian-made APIs marketed overseas -----	121
Figure 25. Market distributions of Indian-made APIs in global market -----	122
Figure 26. Comparison of export values of APIs marketed in each other's country between China and India -----	124
Figure 27. Market growth trend of Indian-made finished drugs marketed overseas and comparison with its Chinese counterpart -----	127
Figure 28. Comparison of the positions of China and India in global drug supply chain -----	137
Figure 29. Growth trend of China's annual spending on healthcare products -----	151
Figure 30. Forecasted future growth trend of Chinese pharmaceutical market -----	153
Figure 31. Forecasted future growth trend of Chinese-made dosage form drugs marketed overseas -----	175
Figure 32. Comparison of forecasted future growths of overseas markets of dosage form drugs between China and India -----	176

List of Case Studies

Case Study 1. Impact of polymorphism on formulated drugs -----	27
--	----

Case Study 2. Examples of formulation capability of Chinese drug companies -----	41
Case Study 3. Examples of Chinese drug companies having passed cGMP certifications of the regulatory authorities of developed countries for their dosage form drug manufacturing facilities -----	45
Case Study 4. Zhejiang Hisun Pharmaceutical Co. Ltd. -----	47
Case Study 5. Zhejiang Huahai Pharmaceutical Co. Ltd. -----	48
Case Study 6. Shenzhen Lijian Pharmaceutical Co. Ltd. -----	49
Case Study 7. More Chinese companies marketing their finished drugs in well regulated markets -----	50
Case study 8. Chinese CROs/CMOs building formulation capability -----	54
Case Study 9. Market share and performance of major pharma companies in emerging markets -----	77
Case Study 10. Major pharma companies licensing sales rights to generic drugs -----	80
Case Study 11. Bayer Schering to conduct joint research on a biodegradable injection drug delivery system with China's National Pharmaceutical Engineering Research Center -----	90
Case Study 12. Sanofi-Aventis relocating and further expanding its China manufacturing facilities -----	91
Case Study 13. Merck starting construction of pharmaceutical packaging plant in Hangzhou -----	92
Case Study 14. West Pharmaceutical opening injection molding factory in Shanghai -----	92
Case Study 15. GSK acquired Nanjing MeiRui Pharma -----	95
Case Study 16. Sanofi-Aventis acquired BMP Sunstone -----	96
Case Study 17. Nycomed acquired Guangdong Techpool Bio-Pharma -----	96
Case Study 18. Cardinal Health acquired Zuellig Pharma China -----	96
Case Study 19. Novartis acquired Zhejiang Tianyuan Biopharmaceutical -----	97
Case Study 20. DSM formed a JV with Sinochem Group -----	97
Case Study 21. Boehringer Ingelheim opened Center of Competence in Shanghai -----	98
Case Study 22. Chinese drug companies in-licensing drug candidates from multinational drug companies -----	115
Case Study 23. Examples of Indian companies sourcing pharma products from China -----	125
Case Study 24. Dr. Reddy's collaborating with SoluBest on formulation development -----	128
Case Study 25. Aurobindo supplying solid dosage and sterile generic products to Astra-Zeneca -----	128
Case Study 26. Hospira acquired generic injectable business from Orchild -----	129
Case Study 27. Abbott Lab acquired Piramal's generic drug business -----	129
Case Study 28. Sun Pharmaceutical Industries forming partnerships on drug formulation with Merck and other Western drug companies -----	129
Case Study 29. Multinational pharma companies licensing drug delivery technologies -----	148
Case Study 30. Chinese drug companies developing controlled-release formulation to reduce side effects -----	160
Case study 31. Examples of Chinese drug companies developing generic drugs focusing on domestic market -----	161

Case study 32. Chinese biotech companies focusing on development of new drug delivery technologies -----	164
Case Study 33. Major pharma companies outsourcing drug formulation -----	172
Case Study 34. Analysis of intrinsic defects in implementation of cGMP in Chinese drug companies -----	179