

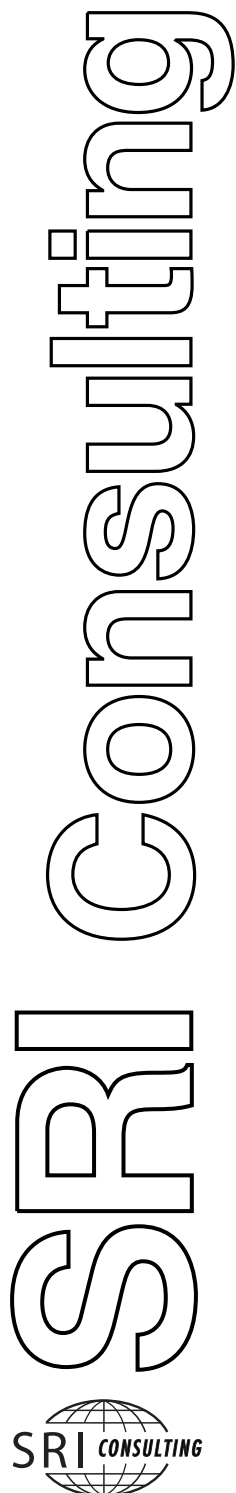
Abstract
Process Economics Program Report 238
CUSTOM CHEMICAL MANUFACTURE
(December 2001)

The manufacture of chemical entities by Custom Manufacturing Organizations (CMOs) is a \$12 billion industry with a projected annual growth rate (AGR) of 8-10%. Growth in this segment of the Fine Chemicals Industry is being fueled by the pharmaceutical industry, both in the production of New Chemical Entities (NCEs) as well as the manufacture of generic drugs.

The decision to outsource the manufacture of a chemical entity versus building a dedicated facility for inhouse production requires an understanding of the differences between a single-product plant where, " *The facility is designed for the process.*" and a multiproduct plant where, " *The process is designed to fit the equipment in the facility.*"

In this report PEP evaluates the production of a chiral pharmaceutical intermediate, L-phenylalanine methylester hydrochloride, and the generic pharmaceutical, fluoxetine, in a dedicated plant versus outsourcing their production.

This report will be of interest to individuals responsible for outsourcing the manufacture of New Chemical Entities (NCEs) in the chemical and pharmaceutical industries as well as those organizations providing outsourcing services.



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CUSTOM CHEMICAL MANUFACTURE

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CONTENTS

1	INTRODUCTION	1-1
2	SUMMARY	2-1
	L-PHENYLALANINE METHYLESTER HYDROCHLORIDE	2-1
	Capital Cost Discussion.....	2-2
	Production Cost Discussion	2-2
	Batch Versus Continuous Production Costs	2-4
	Outsourced Production Costs	2-4
	FLUOXETINE HYDROCHLORIDE	2-4
	Capital Costs Discussion.....	2-4
	Production Cost Discussion	2-5
	SUMMARY	2-7
3	INDUSTRY STATUS	3-1
	PHARMACEUTICAL MARKET	3-1
	CURRENT BUSINESS STATUS.....	3-2
	Pharmaceutical Consolidation	3-2
	CMO RESTRUCTURING	3-2
	Market Share	3-4
	Capacity Increases	3-5
	Drug Approvals Decline.....	3-5
	Decline in Agrochemicals	3-6
	Asian Competition	3-6
	SURVIVAL STRATEGIES	3-6
	Outsourcing Development.....	3-6
	Specialty Niches	3-7
	Hazardous Compounds.....	3-7
	Chiral Chemistry	3-7

CONTENTS (Continued)

Biopharmaceuticals	3-7
Generic Drug Production	3-7
4 DESIGN DISCUSSION	4-1
INTRODUCTION	4-1
Batch versus Continuous Processing.....	4-1
MULTIPRODUCT VERSUS DEDICATED FACILITY	4-2
Dedicated Plant	4-2
Batch Multiproduct Plant.....	4-2
Scheduling	4-3
Storage	4-3
Surge Tanks	4-3
Recycle and Waste Streams	4-3
Solids Recovery.....	4-3
Dryer Selection	4-4
Reactor Suites	4-4
CHEMISTRY	5-2
5 PHENYLALANINE METHYLESTER-HYDROCHLORIDE CONTINUOUS MANUFACTURE.....	5-1
INTRODUCTION	5-1
TECHNOLOGY OVERVIEW	5-1
CHEMISTRY	5-2
PROCESS DESCRIPTION	5-15
Process Overview.....	5-15
SECTION 100 ESTERIFICATION.....	5-15
Section 200 Solids Formation.....	5-16
PROCESS DISCUSSION.....	5-16

CONTENTS (Continued)

Esterification	5-16
Methanol Recovery.....	5-16
Neutralization.....	5-17
Extraction.....	5-17
Waste Generation.....	5-17
Materials of Construction.....	5-17
CAPITAL AND PRODUCTION COSTS	5-17
Capital Costs	5-17
Production Costs	5-18
6 L-PHENYLALANINE METHYLESTER•HYDROCHLORIDE BATCH MANUFACTURE.....	6-1
INTRODUCTION	6-1
TECHNOLOGY OVERVIEW.....	6-1
CHEMISTRY.....	6-2
PROCESS DESCRIPTION	6-18
Section 100-Synthesis.....	6-18
Reactor Preparation	6-18
Charging Reactants.....	6-18
Section 200 - Solids Separation	6-19
Section 300 - Solids Handling	6-20
PROCESS DISCUSSION.....	6-20
Storage Tanks vs. Temporary Storage	6-20
Productivity	6-20
Waste Generation.....	6-20
Materials of Construction.....	6-21
Facility Description	6-21
CAPITAL AND PRODUCTION COSTS	6-21

CONTENTS (Continued)

Capital Costs	6-21
Dedicated Batch Plant Production Costs	6-22
Outsourced Facility versus Dedicated Facility	6-22
7 PRODUCTION OF FLUOXETINE HYDROCHLORIDE	7-1
INTRODUCTION	7-1
TECHNOLOGY REVIEW	7-1
CHEMISTRY	7-3
PROCESS DESCRIPTION	7-9
Process Overview.....	7-9
SECTION 100.....	7-11
Reactor Inerting	7-11
Formation of Carbamate.....	7-11
Carbamate Hydrolysis	7-11
Fluoxetine Formation.....	7-11
Fluoxetine Hydrochloride Formation	7-12
SECTION 200 SOLIDS SEPARATION	7-12
Fluoxetine Hydrochloride Purification.....	7-12
SECTION 300 DRYING AND PACKAGING	7-12
PROCESS DISCUSSION.....	7-20
Process Selection.....	7-20
Productivity	7-20
Waste Generation.....	7-33
Materials of Construction.....	7-33
CAPITAL AND PRODUCTION COSTS	7-34
Production Cost Discussion	7-34
CMO Capital and Production Costs	7-34

CONTENTS (Continued)

8	TECHNOLOGY TRANSFER.....	8-1
	INTRODUCTION	8-1
	TECHNOLOGY TRANSFER PACKAGE (TTP)	
	Process Chemistry	8-1
	Mass Balance	8-2
	Energy Balance	8-2
	Basic Physical Property Data	8-2
	Process Description.....	8-2
	Existing Batch Records	8-2
	Critical Control Points	8-2
	Safety Information	8-3
	Analytical Methods	8-3
	Reaction Completion	8-3
	Waste Disposal.....	8-3
9	PRICING STRATEGIES.....	9-1
	INTRODUCTION	9-1
	Price per hour	9-1
	Price per batch	9-2
	Price per Kilogram	9-2
	SUMMARY	9-2
	APPENDIX A: PATENT SUMMARY TABLES.....	A-1
	APPENDIX B: DESIGN AND COST BASES	B-1
	APPENDIX C: CITED REFERENCES.....	C-1
	APPENDIX D: PATENT REFERENCES BY COMPANY.....	D-1
	APPENDIX E: PROCESS FLOW DIAGRAM.....	E-1

ILLUSTRATIONS

5.1	Custom Chemical Manufacture PM•HCL Continuous Mode Process Flow Diagram	E-3
6.1	Custom Chemical Manufacture Batch Mode PM•HCL Process Flow Diagram	E-9
7.1	Custom Chemical Manufacture Batch Mode Fluoxetine - Hydrochloride Process Flow Diagram	E-13
7.2	Fluoxetine Hydrochloride Block Flow Diagram	7-10
7.3	FLX•HCL Batch Volumes Process Steps	7-24

TABLES

2.1	Capital Related Costs.....	2-2
2.2	L-Phenylalanine Methyl Ester Hydrochloride Manufacture Production Cost Summary	2-3
2.3	Fluoxetine Hydrochloride Production Cost Summary	2-6
3.1	Pharmaceutical Mergers and Acquisitions	3-2
3.2	Custom Chemical M&A Activity	3-3
3.3	Fine Chemical Market.....	3-4
3.4	Capacity Announcements	3-5
3.5	Pharmaceutical Sales and Patent Summary.....	3-8
5.2	Continuous Manufacture of PM•HCL Design Bases and Assumptions	5-4
5.3	Continuous Manufacture of PM•HCL Stream Flow	5-6
5.4	Continuous Manufacture of PM•HCL Major Equipment	5-8
5.5	Continuous Manufacture of PM•HCL Utilities Summary.....	5-10
5.6	Continuous Manufacture of PM•HCL Total Capital Investment.....	5-11
5.7	Continuous Manufacture of PM•HCL Capital Investment by Section.....	5-12
5.8	Continuous Manufacture of PM•HCL Production Costs	5-13
6.2	Batch Manufacture of L-Phenylalanine Methyl Ester Hydrochloride Design Bases and Assumptions.....	6-4
6.3	Production of Phenylalanine Methyl Ester Hydrochloride Salt Material Balance	6-6
6.4	Batch Cycle Chart PM•HCL Production	6-10
6.5	Manufacture of PM•HCL Batch Mode Major Equipment	6-11
6.6	Manufacture of PM•HCL Batch Mode Utilities Summary.....	6-13

TABLES (Continued)

6.7	Manufacture of PM•HCL Batch Mode Total Capital Investment.....	6-14
6.8	Manufacture of PM•HCL Batch Mode Capital Investment by Section.....	6-15
6.9	Manufacture of PM•HCL Batch Mode Production Costs	6-16
6.10	Production Cost Summary PM•HCL Manufacture CMO vs. Dedicated Batch Plant.....	6-23
7.2	Fluoxetine Hydrochloride Batch Manufacture Design Bases and Assumptions.....	7-13
7.3	Production of Fluoxetine Hydrochloride Salt Material Balance.....	7-15
7.4	Fluoxetine Hydrochloride Batch Cycle	7-21
7.5	Fluoxetine Hydrochloride Manufacture Major Equipment	7-26
7.6	Fluoxetine Hydrochloride Manufacture Utilities Summary.....	7-28
7.7	Fluoxetine Hydrochloride Manufacture Total Capital Investment.....	7-29
7.8	Fluoxetine Hydrochloride Manufacture Capital Investment by Section.....	7-30
7.9	Fluoxetine Hydrochloride Manufacture Production Costs	7-31
7.10	Fluoxetine Hydrochloride Waste Summary.....	7-33
7.11	Fluoxetine Hydrochloride Manufacturing Cost Summary.....	7-36