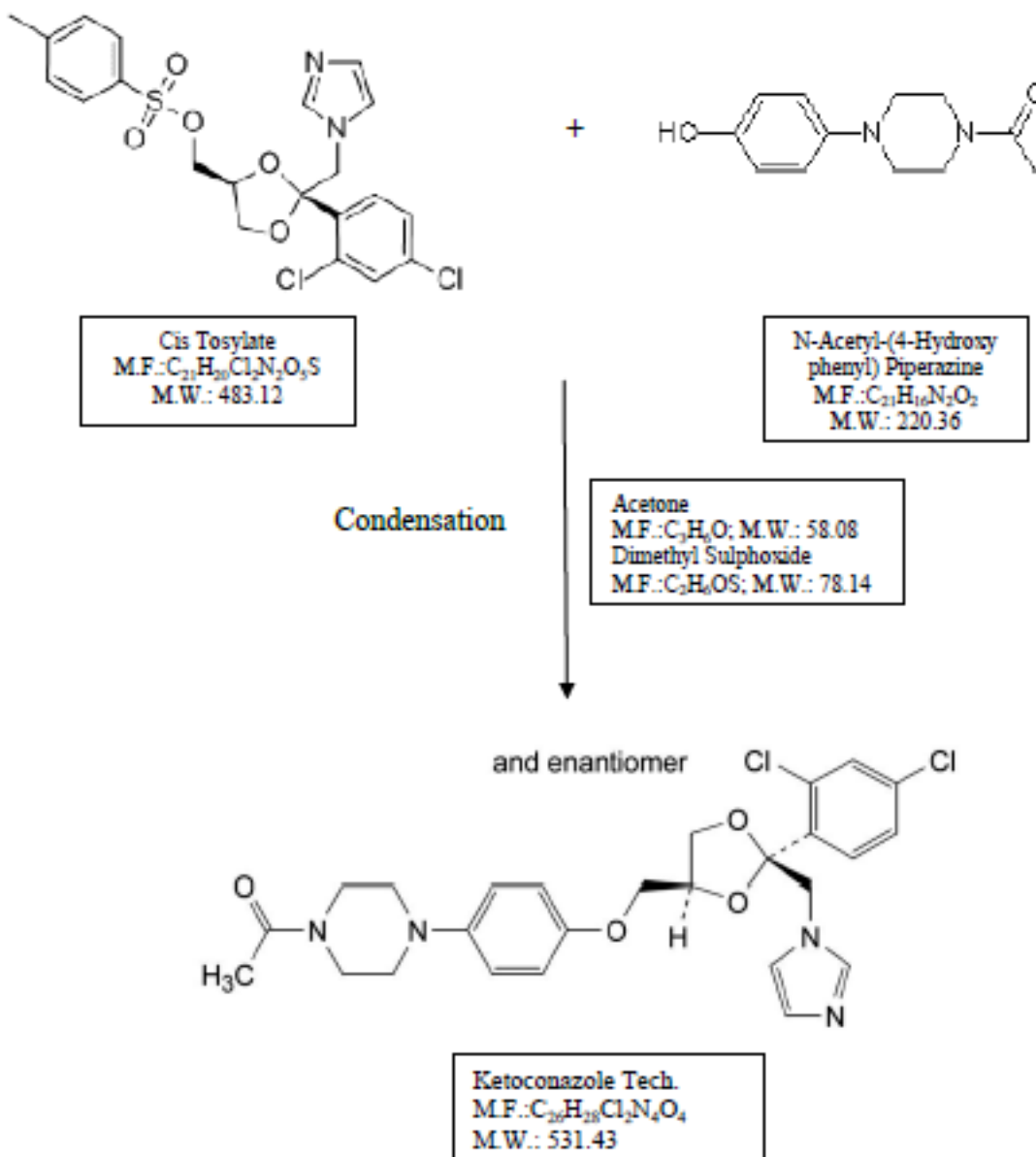


Manufacturing Process Flowchart Ketoconazole, USP (Cat# K1149)

A. Reaction Scheme:

i) Stage-I : Ketoconazole Tech



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

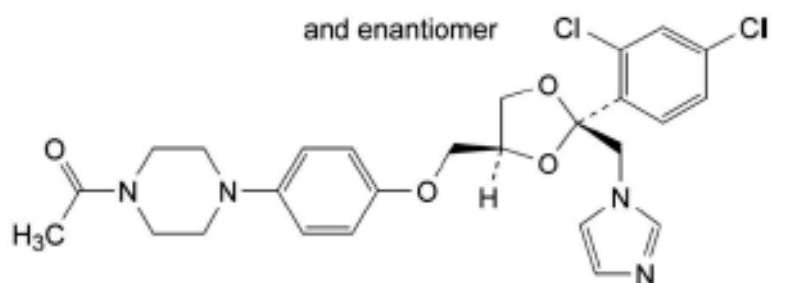
FAX 310.516.9843

3.2. S DRUG SUBSTANCE

3.2. S.2 MANUFACTURE

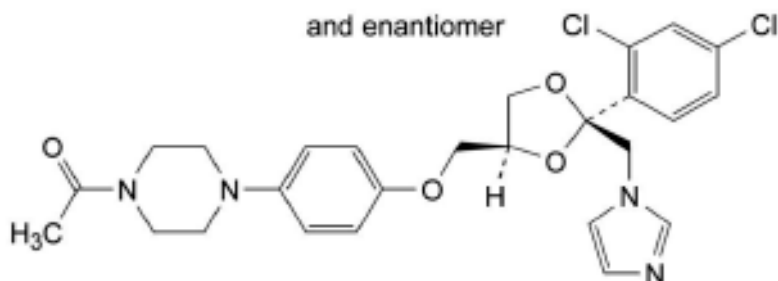
3.2. S.2.2 Description of Manufacturing Process and Process Controls

ii) Stage-II : Ketoconazole (Pharma)



Ketoconazole Tech.
M.F.: $C_{25}H_{28}Cl_2N_4O_4$
M.W.: 531.43

Methanol
M.F.: CH_4O ; M.W.: 32.04



Ketoconazole Pharma
M.F.: $C_{25}H_{28}Cl_2N_4O_4$
M.W.: 531.43

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

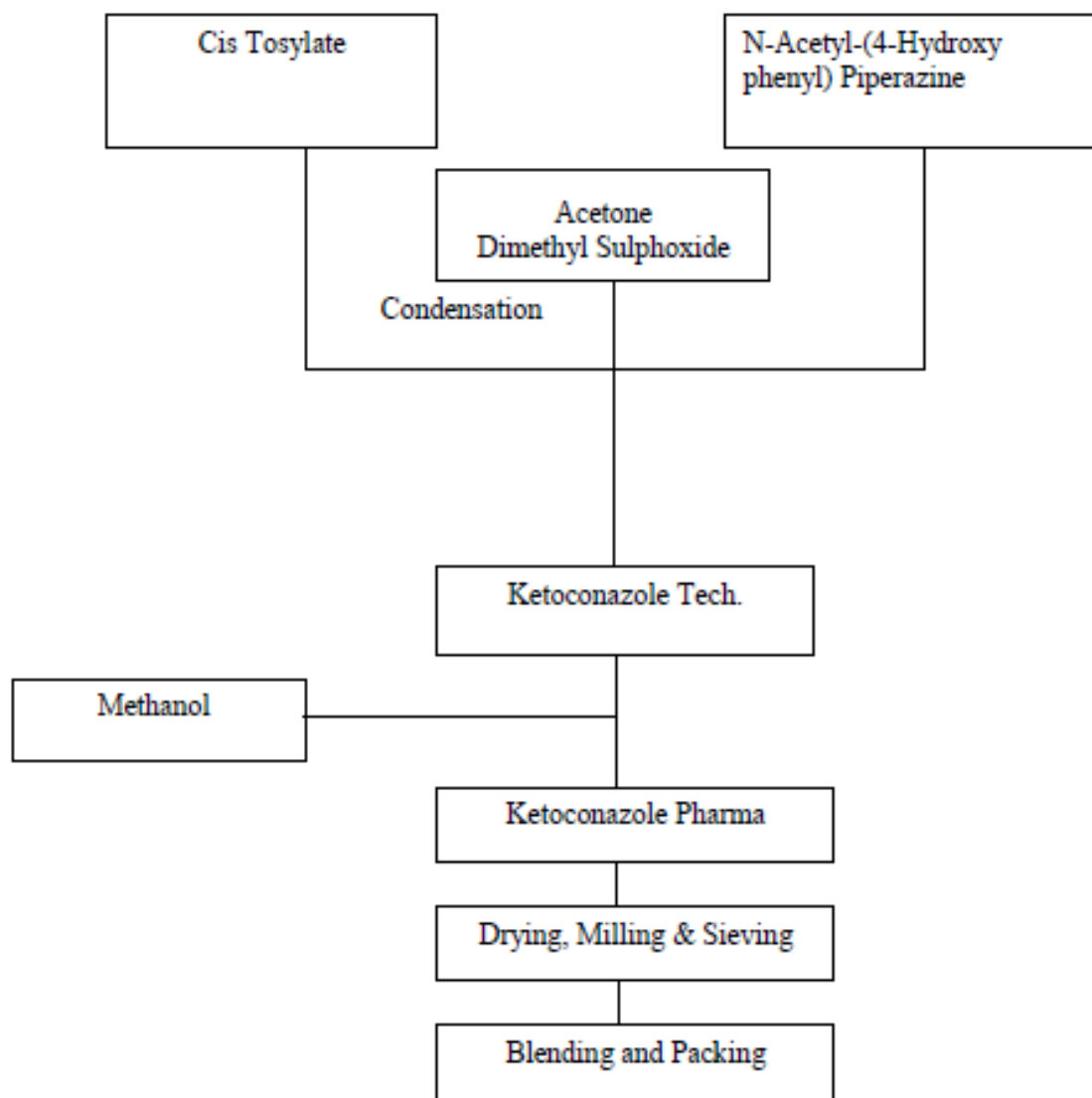
14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

3.2. S DRUG SUBSTANCE
3.2. S.2 MANUFACTURE
3.2. S.2.2 Description of Manufacturing Process and Process Controls
B. Manufacturing process flow Chart:



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843