

# THE FITZPATRICK COMPANY



FITZ<sup>®</sup>MILL



CHILSONATOR<sup>®</sup>

18-20 Nov 2008

Pharmaceutical conference, Poland

Davy Maes

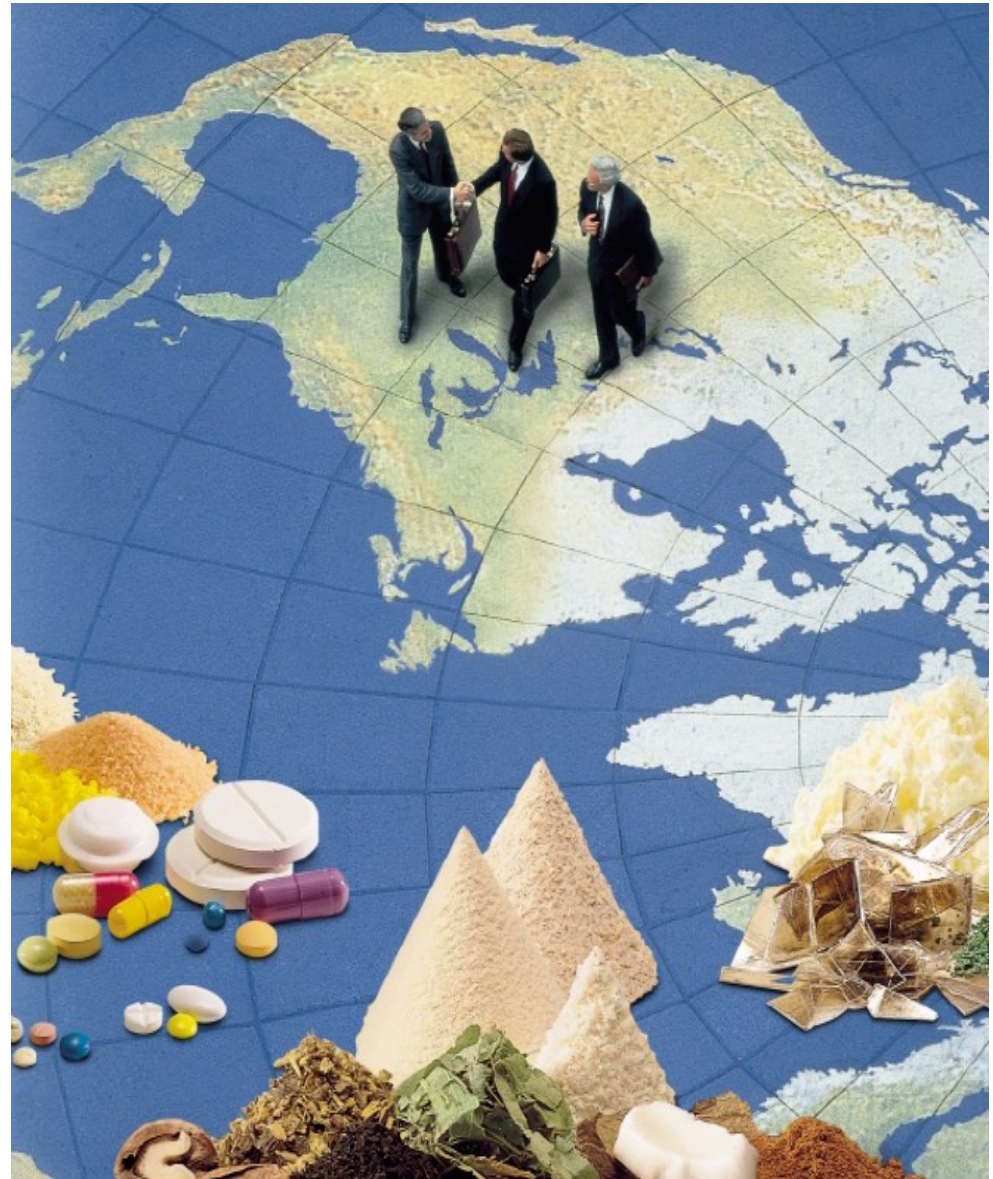


THE FITZPATRICK COMPANY

GLOBAL LEADER IN  
PROCESS TECHNOLOGY

**80 Years experience**

**30,000 Machines sold  
worldwide**



THE **FITZPATRICK** COMPANY – YOUR **PARTNER** IN GRANULATION

FITZ-MILL



FITZ-SIEVE



CHILSONATOR



FITZ CM

# THE FITZPATRICK COMPANY

Providing **Granulation solutions** to the **Pharmaceutical** Industrie, **Worldwide**.

1. Size Reduction: Various milling technologies
2. Dry Granulation: Roll compaction
3. Wet Granulation: Representing Fuji Paudal for low pressure extrusion equipment.

## Innovative designs complying with today's standards

**cGMP** designs

**GAMP**, 21CFR part 11 compliant

**ATEX** compliant

High **containment**:

-Fitzpatrick designed **PCS** system

-Glovebox designs for most stringent containment levels

**WIP, CIP**

Implementing **PAT** on process equipment

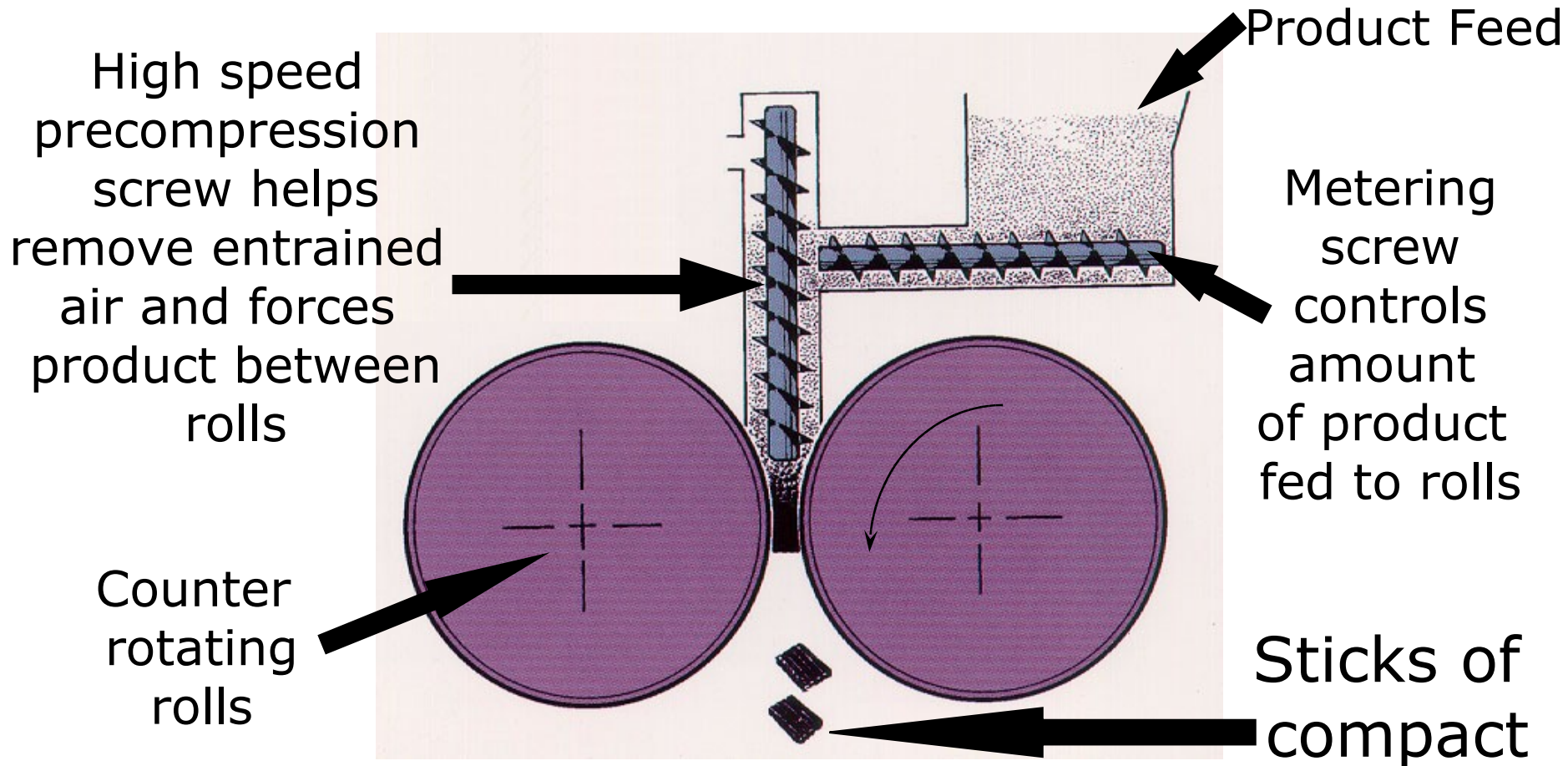


CHILSONATOR<sup>®</sup>

# **1. Dry Granulation by roll compaction**



# Twin Feed Screw System

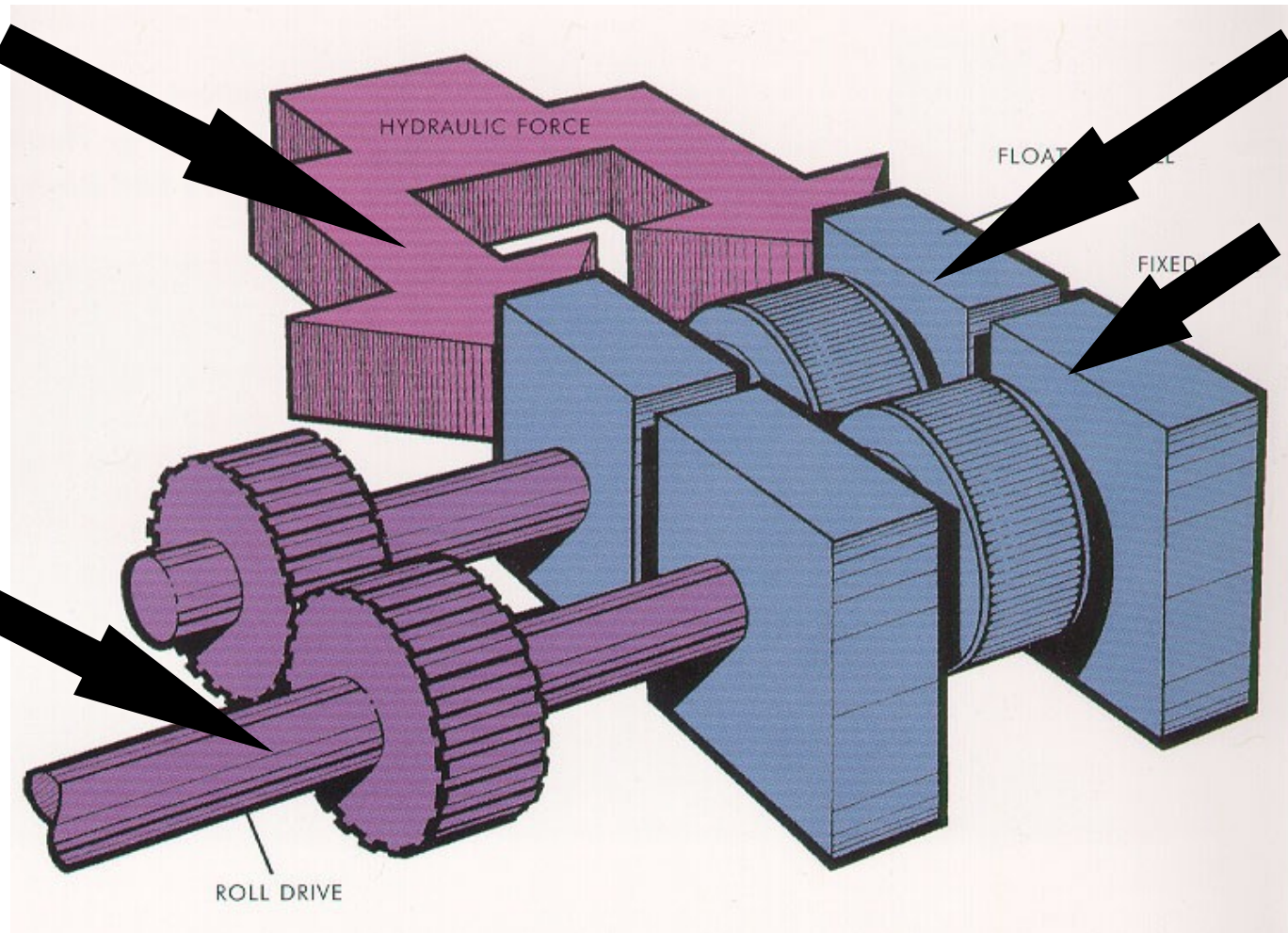


# Rolls Under Pressure

Hydraulic Force

Roll drive

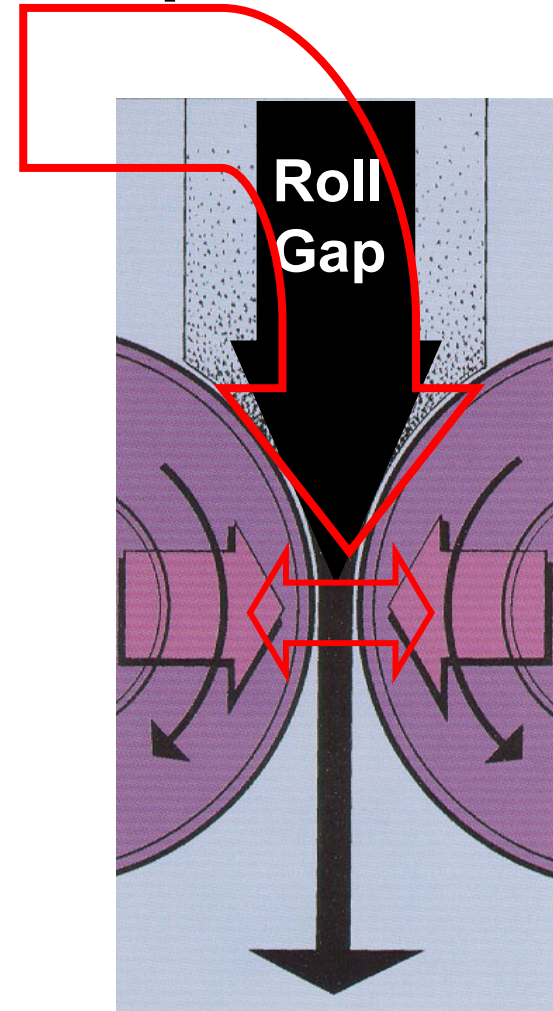
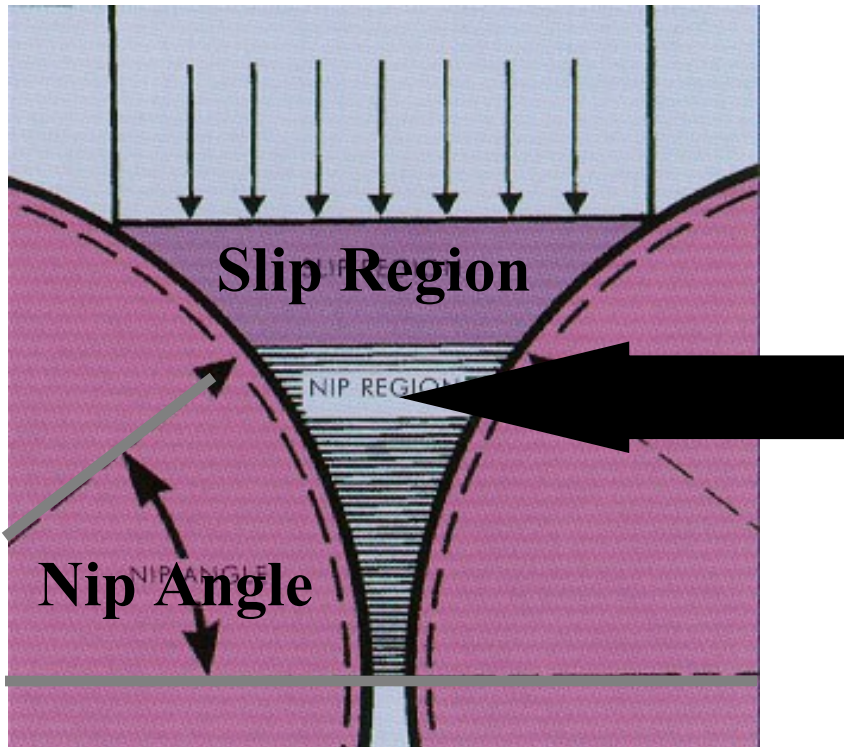
Floating roll  
Fixed roll





# Nip Angle and Roll Gap Control

**Adjust DOSING screw speed**



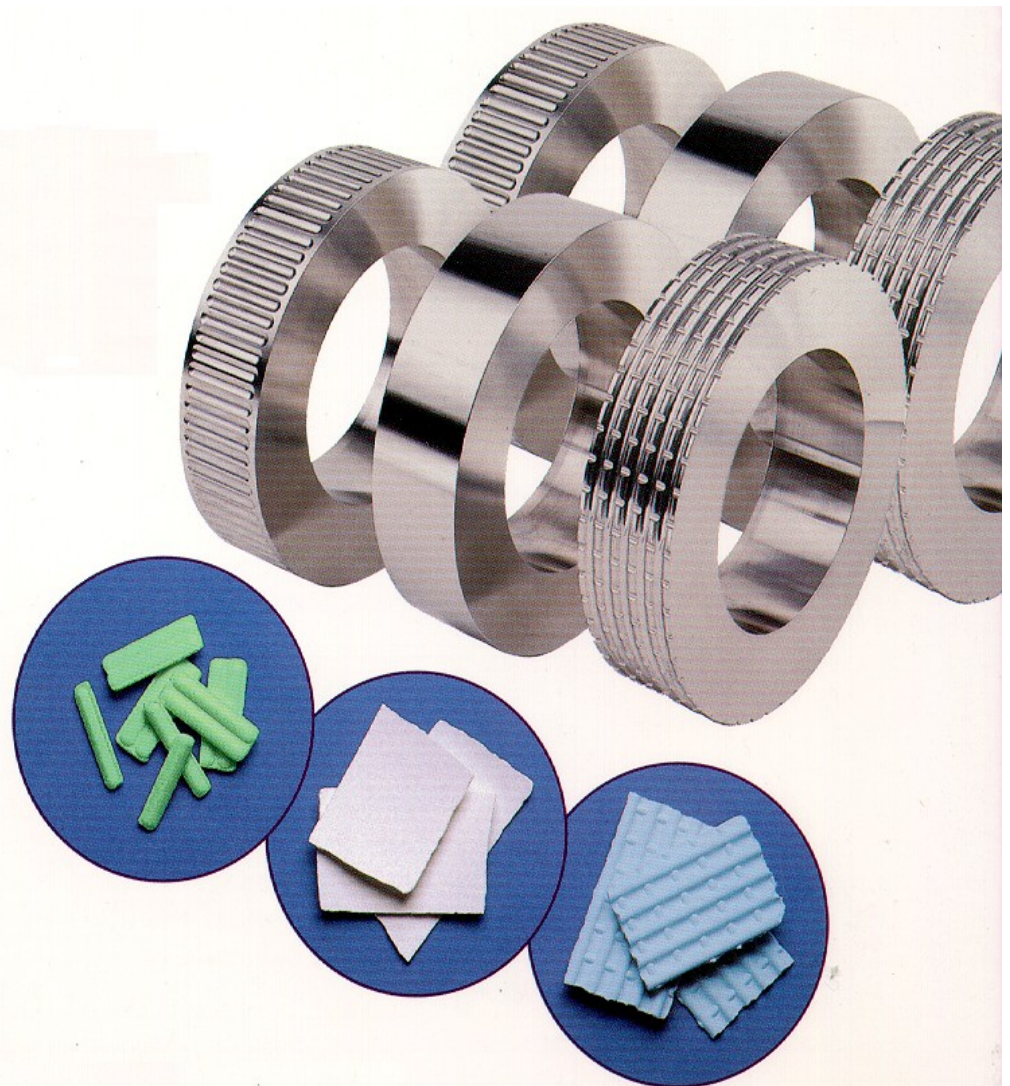
# Roll Surfaces

Pocket axial

Smooth

Circumferential sine

Others



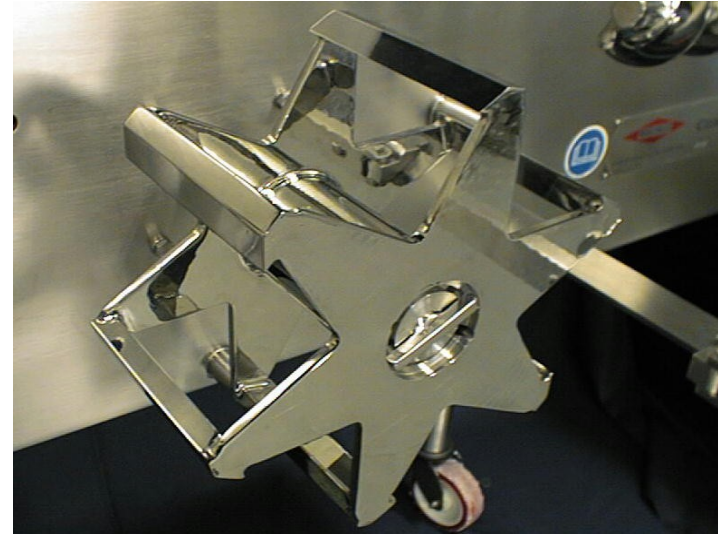
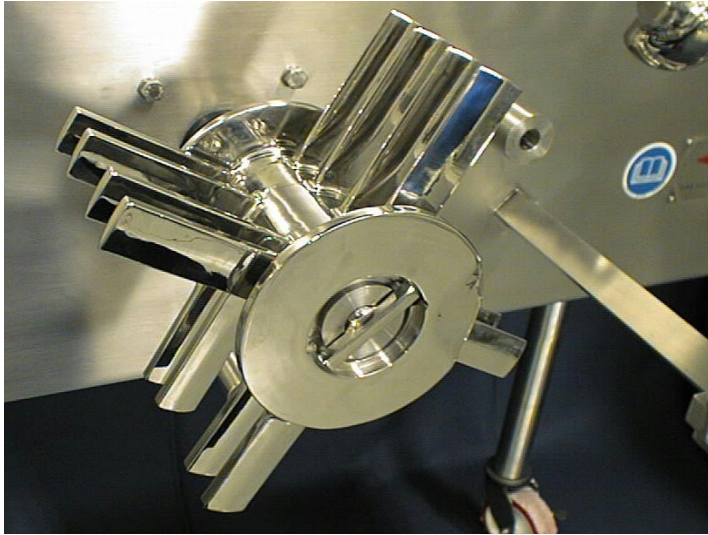
## 2. The FitzMill Comminutor

Controlled particle size reduction

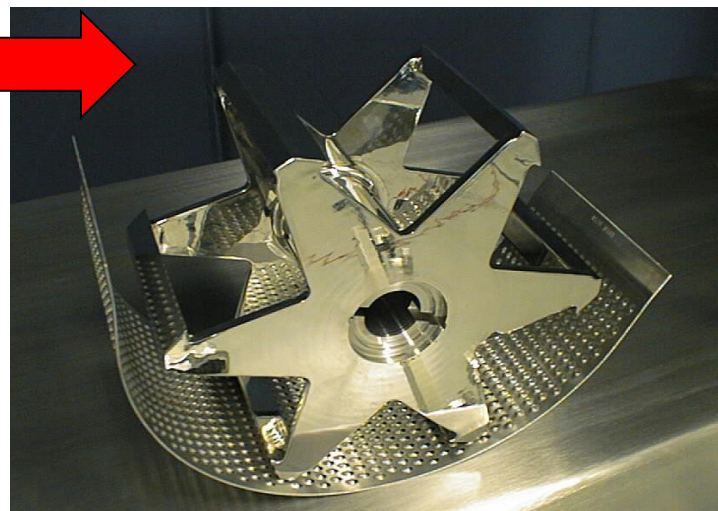
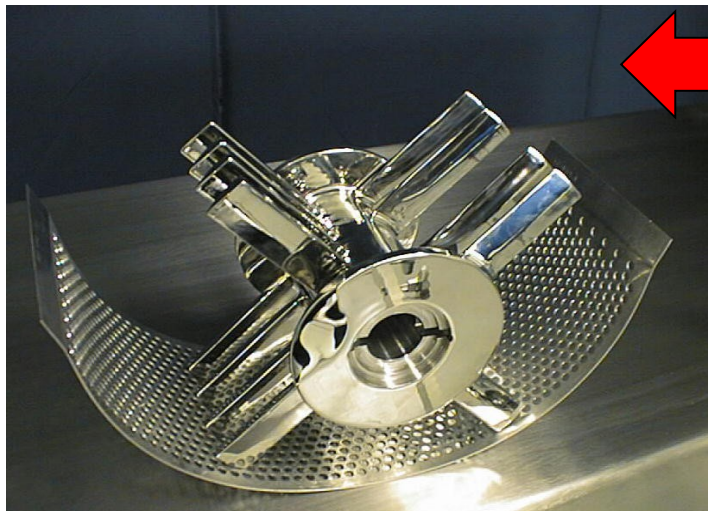
Ultimate FLEXIBILITY for optimal granulation







**interchangeable**







# PRODUCTION CHILSONATOR IR-520



# IR / Pharma design Features:

- cGMP
- “Through the wall” design and “mobile” design
- Separation technical and process parts
- Easy roll removal
- Easy assembly - disassembly < 1hr
- GAMP / 21CFRpart11 compliant (optional)
- Roll force and Torque measurements (optional)
- PCS / containment available (option)
- ATEX compliant (option)
- WIP available (option)
- Full validation package available inclusive on site support.
- PAT (optional)

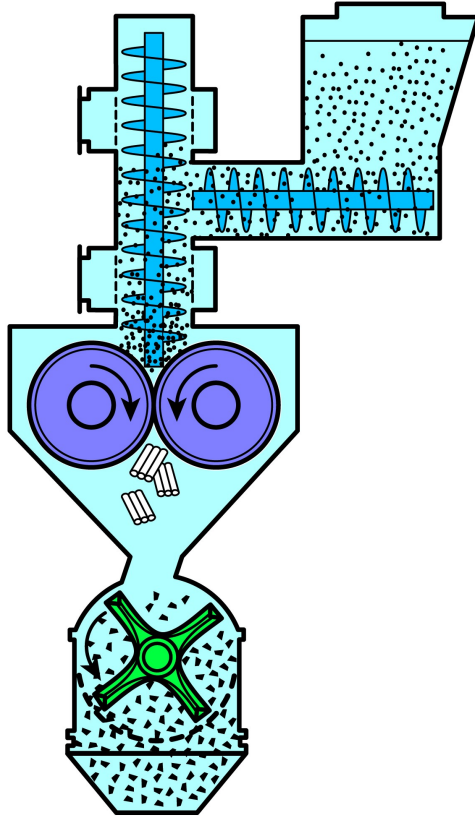
## IR-520 (IN WALL, UP TO 150 kg/hr)





### 3. Next evolution: Contained Granulation

## Containment fundamentals applied to the Chilsonator Roll Compactor



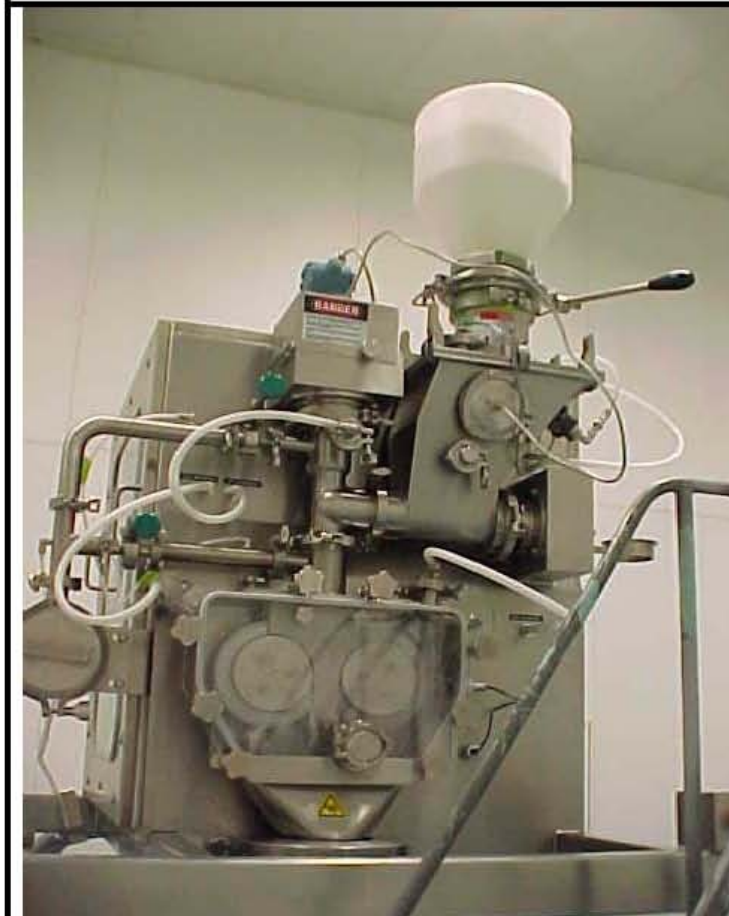
# How to totally contain ?

- Utilize vacuum system to maintain a slight vacuum in the processing area
- Utilize containment systems to contain material at the feed and discharge
- Utilize backpurge system (patent pending) to clean the primary filters in order to operate over extended runs

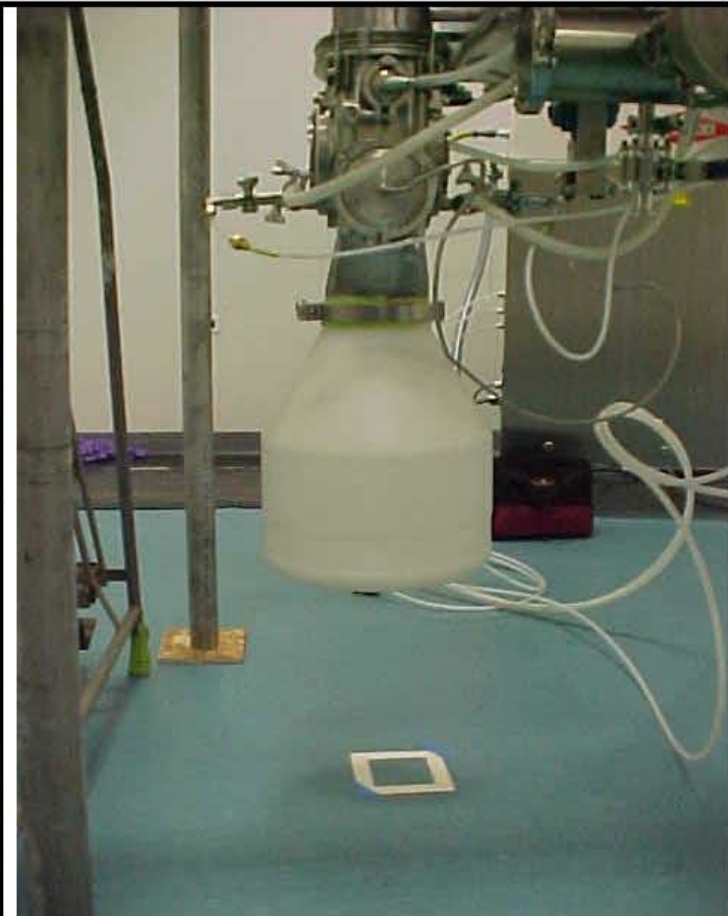
# Working within bands

OEB	Range of OEL( $\mu\text{g}/\text{m}^3$ )	Description
1	>1000	Not harmful, not irritating and/or low pharmacological activity
2	100-1000	Harmful, may be irritant and/or moderate pharmacological activity
3	10-100	Moderate toxic and/or high pharmacological activity
4	1-10	Toxic, may be corrosive, sensitizing or genotoxic and/or very high pharmacological activity
5	<1	Extremely toxic, may be corrosive, sensitizing or genotoxic, and/or extremely high pharmacological activity

# Containment tests



Plastic lactose powder container attached to Fitzpatrick® system.



Close-up view of Fitzpatrick® system powder receptacle and surficial sample location.



# Conclusion

Air testing was performed immediately prior to, during and immediately following each run cycle. Each run lasted approximately 45 minutes.

Testing performed on November 7 & 8, 2006 demonstrated results below the OEL for Category 4 pharmaceuticals.

Photographs of the test room and sampling apparatus are provided in Appendix 4.

Any reference to a specific manufacturer or product in this report does not express NATLSCO's endorsement or recommendation of that product. The reference is made for informational purposes only.

Prepared by:



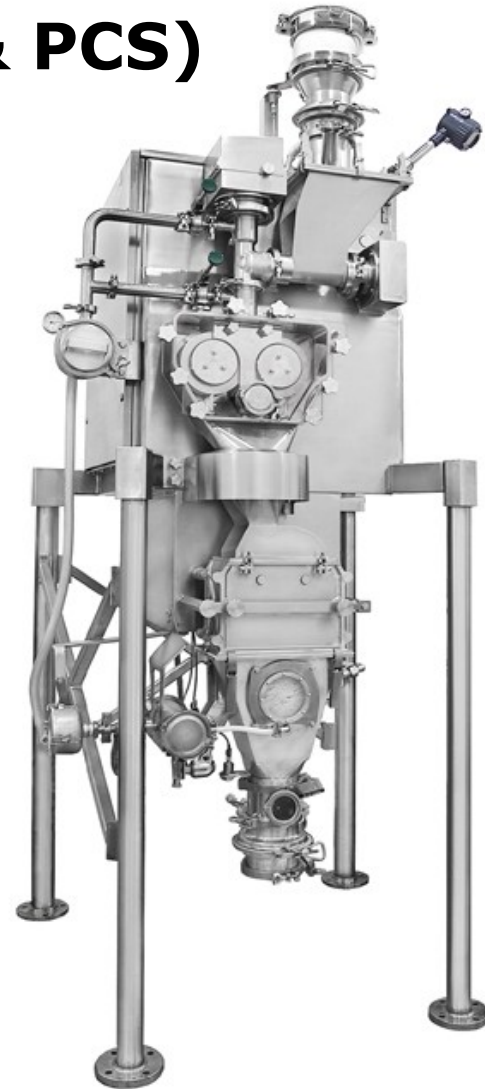
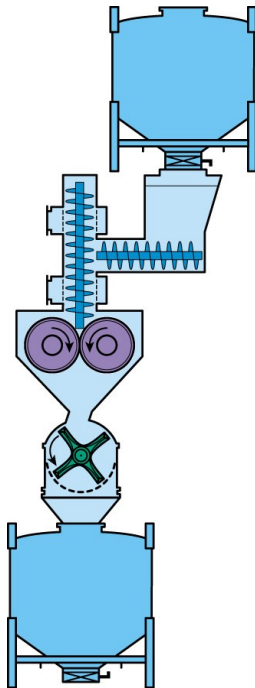
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# Containment - (Bin to Bin & PCS)



The logo for Chilsonator, featuring the name in a white serif font inside a red diamond shape with a white border.

CHILSONATOR®

**Play animation Chilsonator**

**Play WIP Chilsonator**

# FITZPATRICK EUROPE SERVICES

- Organisation Sales Europe, Middle East, Africa
- After Sales, spare parts, technical support
- Project management, documentation, validation
- Process Competence Centre (PCC), test facility







# **Your partner in granulation:**

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Thank  
you!