

The slide features a dark blue background with several decorative pink circles. One circle is an outline, while the others are solid. The text is centered and overlaid on these circles.

Cosmetic Manufacturing

Elizabeth Bilitz

Priscilla Simmons

What is considered a 'cosmetic?'

- The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

-- FD&C Act, Sec. 201 (i)

Cosmetic Standards and Regulations

- Rules regarding Cosmetic Manufacturing:
 - May use almost any ingredient EXCEPT:
 - Those specifically banned such as chloroform, prohibited cattle material, high levels of mercury, etc...
 - Colors not approved for intended use by the FDA
 - If a product uses ingredients not yet proven to be safe, a warning label must be attached
 - Cannot be adulterated or deemed “misbranded”

Good Manufacturing Guidelines

- Provides a checklist for inspection teams
- Located at <http://www.cfsan.fda.gov/~dms/cos-gmp.html>
- Much less strict than drug guidelines
- FDA can inspect manufacturing units for health violations and hazards

Summary of Guidelines



- Most guidelines for the cosmetics industry are voluntary.
- The FDA only has legislature over mislabeling, 'adulterated' (filthy or infected) products, and those that use prohibited materials.
- Cannot order a recall, has 'active roll'
- Hazardous wastes subject to Resource Conservation and Recovery Act (RCRA)

Manufacturing of Cosmetics

- In-house or out-of-house production of cosmetics
- Specifically: Lipstick
 - Made from base ingredients of wax, oil, and antioxidants as well as supplemental products
 - Three-step process:
 - Melting and Mixing
 - Pouring
 - Packaging

LIPSTICK- Melting



- Step 1

- Raw ingredients melted and mixed.
- Solvents are mixed separately from the oils and fats or waxy materials.
- Heating is done in a stainless steel or ceramic container

LIPSTICK-Mixing



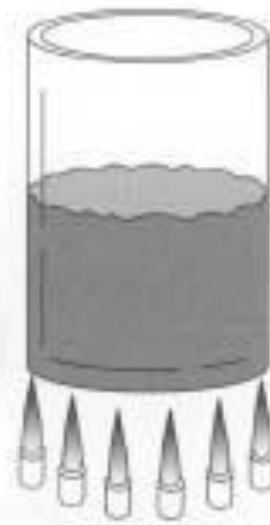
● Step 2

- Solvent solution and liquid oils are mixed with the color pigments.
- The mixture is ground in a roller mill to avoid graininess.
- This process introduces air into the oil and pigment mixture, so mechanical working of the mixture is required.
- The mixture is stirred for several hours; at this point some producers use vacuum equipment to withdraw the air.

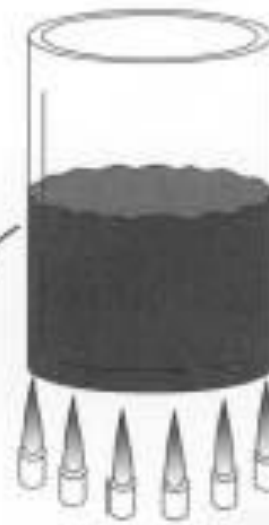
Waxes



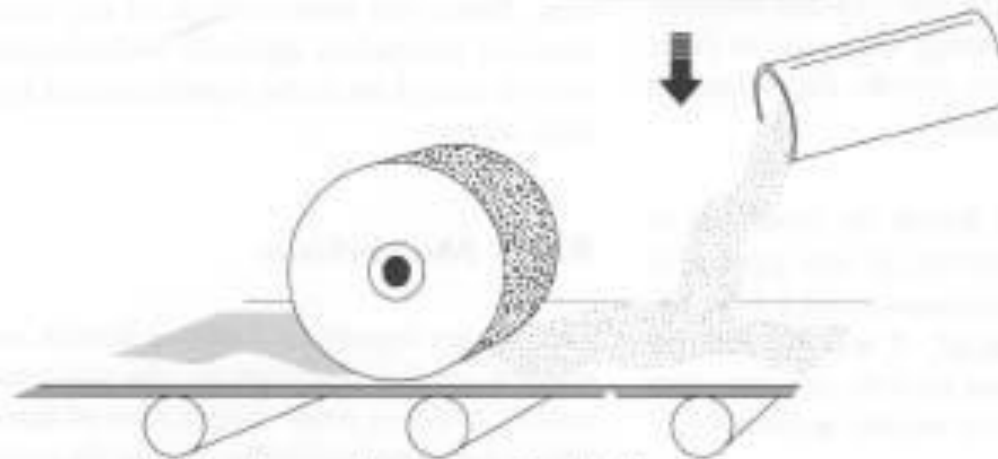
Oils



Solvents



Color pigments
added



Mixture is ground to remove "grainy" feel

LIPSTICK: Mixing cont.

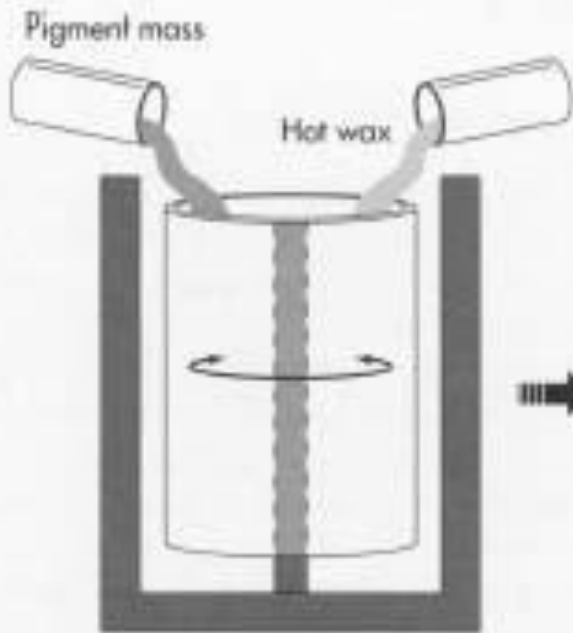
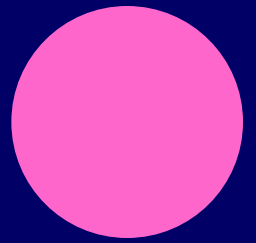
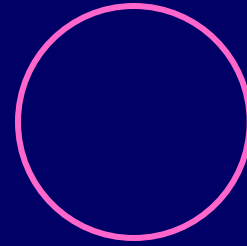
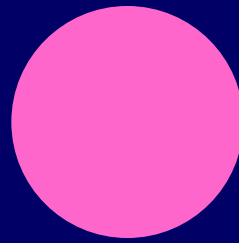
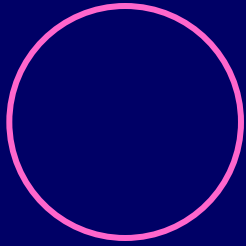
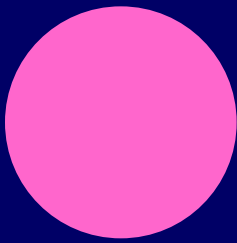


- Step 3

- Pigment mass is ground and mixed, added to hot wax until a uniform color and consistency is obtained.

- Step 4

- Must be agitated to release trapped air. Temperature is maintained.



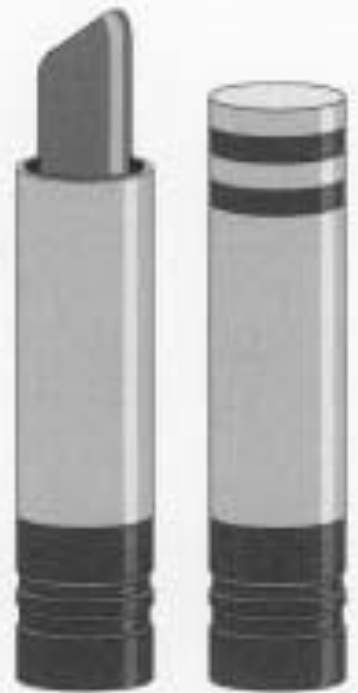
Mixture is agitated
to remove trapped air



Mixture is poured
into tubing molds



Tubes are cooled



LIPSTICK: Molding



- Step 5

- Poured into tube

- High volume batches are generally run through a melter that agitates the lipstick mass and maintains it as a liquid

- Step 6

- Melt is dispensed into tube and shaping

LIPSTICK: Molding cont.



● Step 7

- The lipstick is cooled either by transfer to refrigeration unit (manual batches) or the molds themselves are kept cool.
- Tubes are sealed and 'flamed' to remove pinholes and improve finish.
- Visually inspected

● Step 8

- Reworking by hand with a spatula to remove air

LIPSTICK: Labeling and Packaging

- Step 9

- Labeled to identify batch. Part of automated operation on high volume
- High emphasis on quality and appearance of lipsticks
- Lip balms have less emphasis on this. Everything automated

- Step 10

- Packaging choices
 - Bulk of individually packed
 - Packaging may or may not be highly automated
 - Depends on the end use rather than manufacturing process

Byproducts



- Little to no waste produced
 - Reused when possible
 - Ingredients are expensive
 - In the normal manufacturing process there are no byproducts

Quality Controls



- Lipstick is unique because it is only cosmetic ingested
 - FDA controls ingredients used as well as manufacturing process
 - Mixed and processed in controlled environment
 - Incoming material must be tested.
 - Samples of every batch are saved and stored

Quality continued-Apperance

- Appearance is very important
- Non-standard product is either reworked or scrapped.
- Final inspection of every tube is performed by the consumer, and if not satisfactory, will be rejected at the retail level
- Quality problems at the consumer level have a major impact on the manufacturer.

Quality Continued-Color



- Color control also important measure
- Pigment is checked for every new batch. Controlled when reheated
- Reheating poses problem because color will bleed and is altered every time a reheat is performed
- Colorimetric equipment is used to provide numerical way to control the shades of lipstick.
 - Gives a numerical reading of the shade, when mixed, so it can identically match previous batches
 - Matching of reheated batches is done visually

Quality Tests



- Two Tests

- *Heat Test*

- the lipstick is placed in the extended position in a holder and left in a constant temperature oven of over 130 degrees Fahrenheit (54 degrees Celsius) for 24 hours. There should be no drooping or distortion of the lipstick.

- *Rupture Test.*

- In the Rupture Test, the lipstick is placed in two holders, in the extended position. Weight is added to the holder on the lipstick portion at 30-second intervals until the lipstick ruptures. The pressure required to rupture the lipstick is then checked against the manufacturer's standards. Since there are no industry standards for these tests, each manufacturer sets its own parameters.

Machines Used - Fillers

- Filamatic – One of the most popular machines to manufacture lipstick and other personal care items.





Coolers, Dryers, Fillers...

- Coolers

- Could be more effective at reaching desired temp. quicker.

- Dryers

- Problems with size, keeping clean and maintaining.

- More on Fillers

- Problems with cleaning with ease and changing over to different variations.

Mixers - Primix Corporation

- Marketing and manufacturing of mixing equipment.
- Working on new technology in all mixing fields (Pharmaceuticals, cosmetics, etc) that will distribute and mix nanometer-sized particles throughout the batch; something that has been impossible up until now.

Primix's Designs

- Their Filmix solves many problems in mixing; however, Primix's biggest obstacle is that it can only mix 15ml at a time for small batches and produce only 3L/min from their larger design.





In general...

- Lipstick machines require the following:
 - wave heating/mixing probes
 - mold assembly, transport rail
 - heating/cooling areas
 - fillers
 - drying compartments
 - packaging

Sources



- US FDA /CFSAN

<http://www.cfsan.fda.gov/~dms/cos-toc.html>

- <http://science.enotes.com/how-products-encyclopedia/lipstick>

- <http://www.allproducts.com/machine/lipbar>

- www.cosmeticsbusiness.com

Pharmaceutical Manufacturing

Problems and Improvements

Problems

- Pharmaceutical manufacturing operations are inefficient and costly. Compared to other industrial sectors, the rate of introduction of modern engineering process design principles, new measurement and control technologies, and knowledge management systems is low. Opportunities for improving efficiency and quality assurance through an improved focus on design and control, from an engineering perspective, are not generally well recognized.
- <http://www.fda.gov/cder/gmp/gmp2004/manufSciWP.pdf>
- Development of new more efficient and effective manufacturing process technology often fails to generate any excitement among academics, practitioners and the public at large; since these groups often only come in contact with innovative products and not with the manufacturing process that delivers these products. A recent estimate of potential world-wide cost-savings from efficiency improvement is suggested to be as high as US \$ 90 billion (12).

Improvements

- PAT Initiative
 - ◆ Reducing production cycle times by using on-, in-, and/or at-line measurements and controls.
 - ◆ Preventing rejects, scrap, and re-processing.
 - ◆ Real time release.
 - ◆ Increasing automation to improve operator safety and reduce human error.
 - ◆ Facilitating continuous processing to improve efficiency and manage variability
 - ◆ Using small-scale equipment (to eliminate certain scale-up issues) and dedicated manufacturing facilities.
 - ◆ Improving energy and material use and increasing capacity.
- L.B. Bohle manufactures PAT equipment, achieves 100% accurate measurements in real time on line.

Industry

- Manufacturing costs are very high
 - ◆ 50% materials
 - ◆ 25% Employment
 - ◆ 15% Maintenance and Utilities
 - ◆ 10% Depreciation
 - ◆ (<http://www.fda.gov/cder/OPS/Scherzer-Camp/sld011.htm>)

The result of today's manufacturing processes:

- Large inefficient batch equipment
- Low utilization 30 - 40 % on average
- Capital and labor intensive
- High inventories and excessive warehouse space
- Elaborate HVAC and mechanical segregation
- High transportation costs
- High operating costs
- Low product yields
- Excessive amounts of product non-conformances
- Long lead-times due to stage and final product testing

Main points from this:

- High tech in R & D
- Relatively low tech in Manufacturing
- It matters
 - Big Pharma manufacturing costs are \$ 90 Bn
 - Significantly more than R&D

How can we make a difference?

- Technology exists
 - Near infra-red
 - Laser induced fluorescence
 - Continuous processing
- On line monitoring and control to improve quality
 - Minimize troubleshooting and investigation systems
 - Prevent rather than repair
- Financial drivers are strong
 - 1% yield improvement = \$400 million in savings
- There are significant barriers
 - Cultural
 - Organizational
 - Historical

Opportunities

- Closer links between R&D and Mfg.
- Develop and design manufacturing scale processes ... before registration
- On line measurement and control
- Continuous processing
- Product plants ... not component plants
- Small dedicated facilities

Pharmaceuticals in Chicago

- *Narchem Corporation 3800 West 38th Street
Chicago, IL 60632-3311
Office: (773) 376-8666
Fax: (773) 376-8932
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