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Industrial Encapsulation Processing

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INTRODUCTION AND OBJECTIVES

The over all objectives of this presentation are :

- An introduction to large scale industrial production of controlled release dosage forms.
- A description of the current processes, how they arose and why they are commercially and technically successful.
- A suggested process for developing a commercially successful business based on existing and novel processes.
- The application of this process to a specific technology; a photo-cured microcapsule wall enclosing an acid or a base.

TERMINOLOGY AND BASIC CONCEPTS

These include :

- Worldwide interest and usage.
- Information overload and information obscurity.
- Controlled release and controlled positioning.
- Core/wall morphology.
- Release profiles.
- Science-to-technology transition.
- Test parameters.

MAJOR PROCESSES

These are major industrial processes used both over time and location. The processes briefly described are:

- Simple and complex coacervation.
- Fluid bed coating (Wurster),
- Interfacial polymerization.
- Melt injection and extrusion.
- Pan coating.
- Spray drying.
- Urea-formaldehyde (Polymethyleneurea, PMU).
- Melamine-formaldehyde (MF).
- Seed coating.

DISCUSSION: METHODOLOGY FOR PROCESS DEVELOMENT

The recommended approach is a systems approach described as:

Not only is there but one way of doing things rightly, but there is only one way of seeing them: and that is seeing the whole of them.

The usage of former, idealized process development is used to suggest future development. An example of such prior development is given in the table below :

Former Process Development

BASE TECHNOLOGY	YEAR	ADDITION	CONTROLLED RELEASE
1. Spray Drying of Solids	1872	Emulsified Oils, 1925 Special Disk, 1949, 1987	Spray Dried Flavors Reservoir Structure
2. Extrusion of Synthetic Fibers into a Bath	1920	Flavor Oils, 1957	Sunkist Process
3. Fluid Bed Drying		Top, Side, Bottom Spray Nozzle & Partition 1965	Wurster Coating, Agglomerization
4. Emulsion Polymerization		Add Oil to Plymer 1989	APS Polytrap

DISCUSSION : METHODOLOGY OF PRODUCT DEVELOPMENT

The overall principles here are:

The use of a timeline extending from manufacture of the controlled release dosage form to final consumption.

Initial considerations relative to process election, feasibility, etc.

Deteremination of a release mechanism.

Use public knowledge of existing processes.

EXAMPLE OF THE METHODOLOGY

The objective of this work was to study the release profiles of various acids (citric acid as an example) encapsulated in a polymer matrix obtained by photopolymerization (UV-curing). This study was conducted in collaboration with Novel Polymer System (NPS), an English company who invented the monomer for the encapsulation of citric acid.

This monomer, C3MTO allows the encapsulation of aggressive products such as acids, bases or biocides.

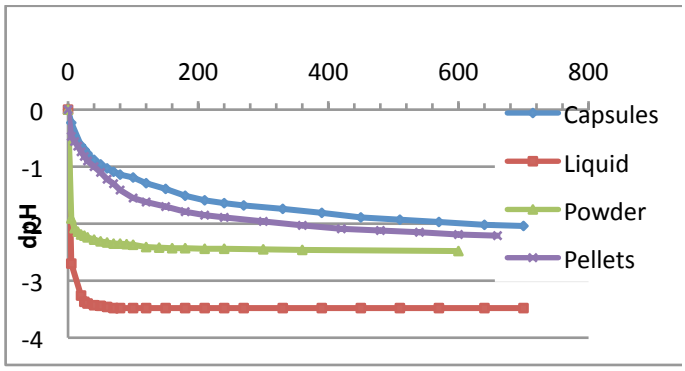
C3MTO is a monomer supplied by Novel Polymer Solutions Series LoVOC 200. LoVOC stands for Low Vola-

tile Organic Compound, this means that its saturated vapor pressure is high and therefore that the vapors are reduced.

The IUPAC name is N, N, N, N-Tetraallylpropane dimethanaminium-1,3-p-toluenesulfonate. The polymerization of C3MTO gives a crosslinked macromolecule which will give a matrix system.

An example of a release profile for this encapsulation system is:

Time in minutes



CONCLUSION

If no well known process solves the problem (satisfies the customer), then what ?

Look for adaptable processes.

Refer to in-house resources and documentation presumably retained as: oral tradition, laboratory note books.

In-house Library, compréhensive and obscure.

In-house documentation of applications know-how.

Compendium of articles (References 1 to 4. See reference table below as an example).

Unexpected results, unlikely results, forgotten technology, adaptable processes.

REFERENCES

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