

Sneak Peek

Analytical Method Development and Validation



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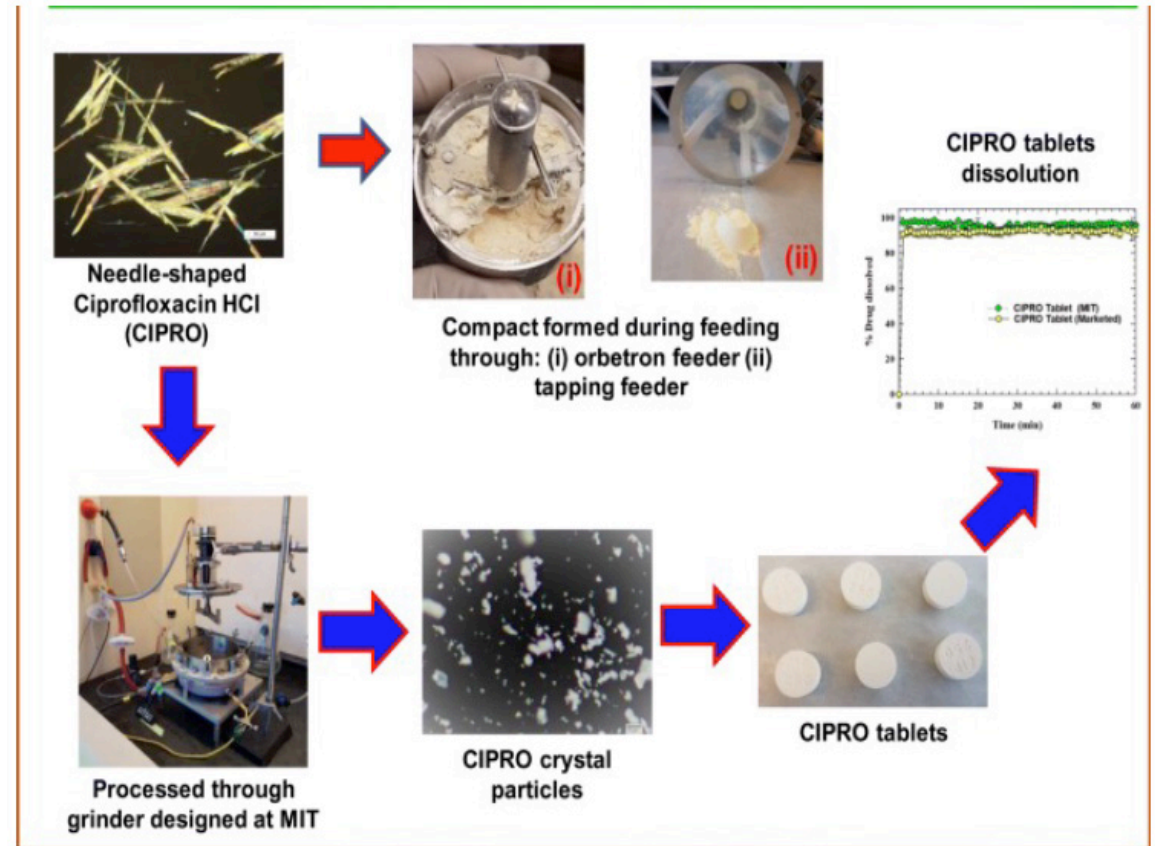


SYMMETRIC

Critical Material Attributes

01

- A material attribute whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality



Post-Approval Change Framework



Risk of Changes	Japan	US	EU
High	Partial change (Application for approval of variation)	Major change (Prior approval supplement)	Type II variation (Application for approval of variation)
Moderate	Minor change (Notification within 30 days after implementation or shipping)	Moderate change 1) Supplement-changes being effected (CBE) in 30 days	Type IB variation (Notification before implementation and MAHs must wait a period of 30 days)
		2) Supplement-changes being effected (CBE)	Type IA_{IN} variation (Immediate notification)
		Minor change (Annual report)	Type IA variation (Notification within 12 months after implementation)
Low			

Benefits of Knowledge Management

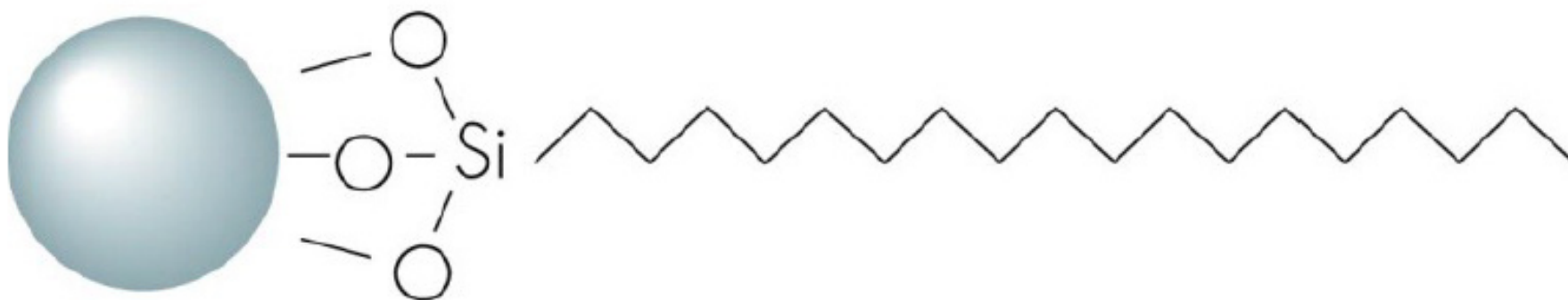
- Learning from past mistakes and successes
- Exploiting existing knowledge to improve products or processes
- Promoting a long-term focus on developing the right competencies and skills and removing obsolete knowledge
- Improving innovation
- Prevents knowledge from being lost

USP <1033> (Bioassays)



- <1032> deals with bioassay development
- <1033> provides guidance on:
 - Validation protocol
 - Documenting results
 - Validation approach
 - Relative accuracy, specificity, IP (which incorporates repeatability), and range
 - Acceptance criteria
 - “When there is an existing product specification, acceptance criteria can be justified (based on) the risk that measurements may fall outside the specification”
 - Monitoring (e.g. by statistical process control)

- Tri-functional bonded C18 groups bound to a very pure silica substrate provide a very hydrophobic and inert surface
- This type of column is the usual starting point for reversed phase method development



Registration

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