Thommen Furler

ERBApharm® et Xcipharm®: différences principales

Parameter	ERBApharm®	Xcipharm®
Quality System	ISO 9001	IPEC guidelines
Validated cleaning procedure or dedicated equipment	X	X
Traceability of raw material / finish good	X	X
Traceability of primary packaging / finished good	na	X
Labels Management	line clearance	reconciliation
Analysis	analytical reduction plan (critical parameters for each batch, full analysis once a year)	full analysis for each batch
Certificate of analysis	as currentp	in addition to current: name and address of the raw material producer, production date, packaging date in CER's premises
Batch release by AQ service	X	X
Samples library	raw material for 1 year	raw material for 1 year finished goods: shelf life + 1 year
Change control notification	on request/QA	systematic
Shelf or retest date	X	X
Stability study	na	X
BSE/TSE certificate	on request (if available from the producer)	systematic
Residual Solvents Certificate	on request (if available from the producer)	systematic
GMO Certificate	on request (if available from the producer)	systematic
Specification summary / Non-Disclosure Agreement	on request	systematic
ICHQ3D	na	systematic
Supply chain and risk assessment	na	X
French MOH registration	na	X

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