

# Standard vs regulated products

Catalog number	C-*	EQ-C-*	PE-C-*
Stock keeping	off-the-shelf	off-the-shelf	Customized CRD-process, made-to-order
Intended use	Intended for <i>in vitro</i> research use only, not for diagnostic or therapeutic procedures.	Intended for research use or further manufacturing, not intended for direct administration to humans or animals.	Intended for research use or further manufacturing, not intended for direct administration to humans or animals.
Final product / production and quality control			
Manufactured according to SOP	yes	yes	yes
Documented batch record (confidential)	yes	yes	yes
QC batch-specific	yes	yes	yes
Product release batch-specific	yes	yes	yes
Storage of retain samples according to shelf life	yes	yes	yes
Guarantee of functionality regarding PromoCell's test system	yes	yes	yes
Customer formulation possible	yes	no	on request
Additional QC possible	no	no	yes
Packaging			
Package size others than standard package size available	on request	no	yes
Labeling, additional information	no	no	yes
Tamper Seals	no	yes	yes
Raw materials			
Guarantee of functionality regarding PromoCell's test system	yes	yes	yes
Guarantee of consistent supply chain	no	yes	yes
Guarantee of consistent regulatory status of raw materials	no	yes	yes
Change control			
Risk assessment regarding regulatory requirements in case of changes	N/A	yes	yes
Information about changes in compliance with IPEC Change Guide	no	yes	Yes

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Information			
Product manual	yes	yes	yes
MSDS	yes	yes	yes
Certificate of analysis, batch-specific	yes	yes	yes
Excipient quality assessment file	no	yes	yes
GMP certificate	no	yes	yes
Certificate of compliance / conformity	on request	yes	yes
TSE / BSE certificate	no	yes	yes
Microbial and virus safety certificate	no	yes	yes
GMO certificate	no	yes	yes
Certificate of origin for final products (Manufacturing site)	on request	yes	yes
CoA customized	no	no	yes
Information about ingredients (NDA is needed)	no	no	on request
Audits			
EXCiPACT® audit report will be shared	no	yes	yes
In-person audits	no	on request	yes



ISO 9001:2015 CERTIFIED COMPANY

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