

# Research use only vs regulated products

	Research use only products	Regulated products	
Catalog number	C-*	EQ-C-*	PE-C-*
Stock keeping	off-the-shelf	off-the-shelf	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 for direct administration to humans or animals.	Intended for research use or further manufacturing, not for direct administration to humans or animals.
<b>Quality Management System</b>			
Manufactured in compliance with ISO 9001:2015	✓	✓	✓
Manufactured in compliance with EXCiPACT™ Certification standard for Pharmaceutical Excipients (GMP)	-	✓	✓
<b>Final product / production and quality control</b>			
Manufactured according to SOP	✓	✓	✓
Documented batch record (confidential)	✓	✓	✓
QC batch-specific	✓	✓	✓
Product release batch-specific	✓	✓	✓
Storage of retain samples according to shelf life	✓	✓	✓
Guarantee of functionality regarding PromoCell's test system	✓	✓	on request
Customer formulation possible	✓	-	on request
Additional QC possible	-	-	✓
<b>Packaging</b>			
Package size others than standard package size available	on request	-	✓
Labeling, additional information	-	-	✓
Tamper seals	-	✓	✓
<b>Raw materials</b>			
Guarantee of functionality regarding PromoCell's test system	✓	✓	on request
Guarantee of consistent regulatory status of raw materials	-	✓	✓
<b>Change control</b>			
Risk assessment regarding regulatory requirements in case of changes	-	✓	✓
Information about changes in raw material specifications, which may impact regulatory status	-	✓	✓
<b>Information</b>			
Product manual	✓	✓	-
MSDS	✓	✓	✓

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Information on Certificate of Analysis (CoA), batch-specific	Color / Clarity Microbial Contamination Functionality	Color / Clarity Microbial Contamination Functionality pH Osmolality Endotoxin <sup>+</sup> Mycoplasma	Color / Clarity Microbial Contamination Functionality <sup>++</sup> pH <sup>++</sup> Osmolality <sup>++</sup> Endotoxin <sup>++</sup> Mycoplasma <sup>++</sup> additional tests <sup>++</sup>
Excipient Quality Assessment File (EQAF) for catalog products	-	✓	-
Customer Requirement Document (CRD) for Risk Assessment and Quality Agreement for Customized Products	-	-	✓
GMP certificate	-	✓	✓
Certificate of compliance / conformity	on request	✓	✓
TSE / BSE certificate	-	✓	✓
Microbial and virus safety certificate	-	✓	✓
GMO certificate	-	✓	✓
Certificate of origin for final products (Manufacturing site)	on request	✓	✓
CoA customized	-	-	✓
Information about ingredients (NDA is needed)	-	-	on request
<b>Audits</b>			
EXCiPACT™ audit report will be shared	-	✓	✓
In-person audits	-	✓	✓

\* product catalogue number

+ only for basal media

++ defined in CRD



ISO 9001:2015 CERTIFIED COMPANY

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