

Research use only vs regulated products

	Research use only products		Regulated products	
Catalog number	C-*	C-8*	EQ-C-*	PE-C-*
Stock keeping	off-the-shelf	made-to-order [#]	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 <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.
Quality Management System				
Manufactured in compliance with ISO 9001:2015	✓	✓	✓	✓
Manufactured in compliance with EXCiPACT™ Certification standard for Pharmaceutical Excipients (GMP)	-	-	✓	✓
Final product / production and quality control				
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	-	on request
Additional QC possible	-	✓	-	✓
Packaging				
Package size other than standard package size available	on request	✓	-	✓
Labeling, additional information	-	-	-	✓
Tamper seals	-	-	✓	✓
Raw materials				
Guarantee of functionality regarding PromoCell's test system	✓	-	✓	on request
Guarantee of consistent regulatory status of raw materials	-	-	✓	✓
Change control				
Risk assessment regarding regulatory requirements in case of changes	-	-	✓	✓
Information about changes in raw material specifications, which may impact regulatory status	-	-	✓	✓
Information				

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

defined in CRF

* product catalogue number

+ only for basal media

++ defined in CRA



ISO 9001:2015 CERTIFIED COMPANY

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