

Recombinant Human R-Spondin1

Cat. No.: GMP-CX83

GMP Grade

Animal-free, Ampicillin-free

01/ Description

R-Spondin 1 (RSPO1) is a secreted protein that contains two FU (furin like) repeat sequences and one TSP type I domain, belonging to the R-spondin family. Regardless of gender, RSPO1 is required for early development of Gonad. This phenomenon was discovered only 11 days after fertilization in mice. In order to induce cell proliferation, it collaborates with WNT4. They help stabilize β chain proteins, thereby activating downstream targets. RSPO1 is necessary in female sexual development. It enhances Wnt/ β -catenin pathway is used to combat male sexual development. During the critical gonadal stage, 6 to 9 weeks after fertilization, the ovaries are upregulated while the testes are downregulated. RSPO1 may help to treat mucositis characterized by oral inflammation. For cancer patients with head and neck tumors, they often suffer from this inflammatory pain with chemotherapy and radiation therapy.

Recombinant Human RSPO1 is expressed by mammalian cells, and is produced with raw materials of pharmaceutical applicable level. The host protein residue, nucleic acid residue and common pathogens are strictly controlled, and the production and quality management procedures of the product comply with GMP regulations to ensure the traceability of the production process and all raw materials.

02/Quality Elements

Item	Standard
Appearance	White porosity
Reconstitution	Totally dissolve in stated time
Visible particle	Conform to ChP
pH value	6.9–7.9
Purity	$\geq 95\%$
Bioactivity	$\geq 2.0 \times 10^5$ IU/mg
Endotoxin	< 10 EU/mg
Host protein	$\leq 0.005\%$
Exogenous DNA residue	≤ 100 pg/mg
Mycoplasma test	Negative
Sterility test	Conform to ChP

Annotation: ChP refers to the Pharmacopoeia of the People's Republic of China.

03/ Complying to following regulations

- (1) 《Good Manufacturing Practice of Medical Products (2010 version, NMPA)》.
- (2) 《GMP Appendix – Cellular therapeutic product》 National Medical Products Administration.
- (3) 《Pharmacopoeia of the People's Republic of China》 2020 version, National Pharmacopoeia Commission.
- (4) USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products

- (5) USP Chapter <92>, Growth Factors and Cytokines Used in Cell Therapy Manufacturing
- (6) Ph. Eur. General Chapter 5.2.12, Raw Materials of Biological Origin for the Production of Cell-based and Gene Therapy Medicinal Products

04/ Application

In-vitro cultivation of various types of cell.

05/ Transport & Storage

Lyophilized product in powder form, 2-8°C temperature required for transport.

Storage at -20 ± 5 °C expiration date labeled on bottle.

06/ Precaution

- (1) Make sure the product properly stored and none expired before using.
- (2) Please use water for injection for reconstitution, to a concentration > 100 µg/ml.
- (3) Sterile condition without pyrogen is required for reconstitution, re-aliquoting, dilution.
- (4) After reconstitution, aliquoted solution vials should be stored at -70°C and minimize freeze-thaw cycles preventing denaturation of protein.

07/Related Products

Cat. No.	Product Name
GMP-C687	Recombinant Human Activin A
GMP-C046	Recombinant Human FGF basic
GMP-C029	Recombinant Human EGF
GMP-CA82	Recombinant Human Flt-3 Ligand
GMP-CJ72	Recombinant Human HGF
GMP-CF63	Recombinant Human IL-3
GMP-C009	Recombinant Human IL-6
GMP-CH73	Recombinant Human KGF
GMP-C023	Recombinant Human LR3 IGF-1
GMP-C099	Recombinant Human OSM
GMP-C199	Recombinant Human PDGF-BB
GMP-CI56	Recombinant Human sCD40 Ligand
GMP-CD53	Recombinant Human SCF
GMP-CA59	Recombinant Human TGF-beta 1
GMP-CJ95	Recombinant Human TPO
GMP-C395	Recombinant Human Vitronectin