

PL3012: Patent applications using CG-MALS

Summary

This document lists patents and patent applications using CG-MALS. Where patent applications have been submitted to multiple countries or organizations, only one is mentioned. Unless otherwise noted, CG-MALS was used to determine the second virial coefficient or similar measures of colloidal stability in order to optimize a biotherapeutic formulation.

Insulin

CG-MALS was used to determine M_w of a long-acting derivative of a human insulin analogue, in order to identify the formulation conditions needed to preserve optimal oligomerization properties for sub-cutaneous delivery.

- [Insulin containing pharmaceutical compositions](#)
Norrman, M. et al. US 2019/0183979
<https://patents.google.com/patent/US20190183979A1>
- [Insulin containing pharmaceutical compositions](#)
Norrman, M. et al. US 2018/0169190
<https://patents.google.com/patent/US20190183979A1>
- [Insulin containing pharmaceutical compositions](#)
Norrman, M. et al. US 2018/0303908
<https://patents.google.com/patent/US20190183979A1>

Therapeutic proteins

- [Tissue plasminogen activator formulation](#)
Mina, R.A. US20230310717A1
<https://patents.google.com/patent/US20230310717A1/en>
- [Collagenase formulations and methods of producing the same](#)
Sukuru, K. WO2020142701
CG-MALS was used to quantify the effect of formulation pH and excipients on colloidal stability in order to optimize the formulation.
<https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2020142701>

Fusion proteins

- [Stable hybrid Fc fusion G-CSF formulation](#)
Öncel, Hatice et al. WO 2019 / 212429
<https://patents.google.com/patent/WO2019212429A2>

Bispecific antibodies

- [ANTI-TNF- / ANTI-IL-23 IgG BISPECIFIC ANTIBODIES](#)
Demarest, S. J., Na, S., Boyles, J. S. & Chai, Q. US 2019 / 0040156
CG-MALS was used to determine M_w of immune complexes consisting of tumor necrosis factor alpha (TNF α) and traditional or bispecific anti-TNF α antibodies, demonstrating lower immunogenic potential.
<https://patents.google.com/patent/US20190040156A1>

- [Formulation optimization for bispecific antibodies](#)

Zhou, C. et al. US20210054050A1

<https://patents.google.com/patent/US20210054050A1/en>

Monoclonal antibodies

- [Pharmaceutical composition of a humanized anti-cd40 antibody](#)

Kranze, J. US20230203179A1

CG-MALS demonstrates that KPL-404 readily forms reversible dimers and higher-order oligomers that are not detected by SEC, but Formulations A, B and C inhibit those oligomers.

<https://patents.google.com/patent/US20230203179A1/en>

- [Therapeutic Protein Selection in Simulated In Vivo Conditions](#)

Kim, D, and Marlow, M. US20200064353A1

CG-MALS was used to establish the validity of a high-throughput method for simulating protein-protein interactions effects in vivo.

<https://patents.google.com/patent/US20200064353A1/en>

- [Concentration-dependent self-interaction assay](#)

Marlow, M. et al. US20220357335A1

CG-MALS is used to assay interactions for optimal high-concentration formulations.

<https://patents.google.com/patent/US20220357335A1/en>

- [Aqueous pharmaceutical formulations](#)

Suchy, D.M. et al. WO 2018/091729

<https://patents.google.com/patent/EP3541413A2>

- [Stable anti-cleaver-1 antibody formulation](#)

Mandelin, J. and Vainio, M. US20230235046A1

<https://patents.google.com/patent/US20230235046A1/en>

Polymers

- [Cationic formation stabilizers compatible with anionic friction reducing polymers](#)

Benoit, D.N. et al. US11767458B2

The effect of KCl on the polymeric radius was studied using the CG-MALS system. CG-MALS is noted to possess advantages compared to conventional GPC: it uses lower concentrations than what is injected with GPC, helping ensure that the polymer molecules are not aggregated, and results are achieved much more quickly with significantly less mobile phase use.

<https://patents.google.com/patent/US11767458B2/en>



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