Citation Evidence Report

EB-1A Petition — Original Contributions of Major Significance

8 CFR § 204.5(h)(3)(v) · Criterion 5

Varsha V Nair

Amgen

Google Scholar profile

Generated 2026-05-21 by CiteMap. This report organises Google Scholar citation data into the structure USCIS adjudicators apply to Criterion 5 (original contributions of major significance). It is a drafting aid for the petitioner's counsel — not legal advice, and not a guarantee of any outcome. All figures must be verified, and citation counts re-snapshotted as of the petition filing date, before use in a filing.

A. Overview & Filtering Statement

96	96	11	3
Citing papers mapped	Citation edges	Home papers mapped	h-index (GS)

Filtering statement — methodology & limits

Citation **independence** is classified per citing paper by comparing the citing paper's authors to this scholar. *Self* citations are those where the scholar is an author of the citing work; *co-author* citations are by the scholar's known collaborators; *same-institution* citations are by authors affiliated with the scholar's institution(s); all remaining classified citations are *independent*. Per AAO practice, only independent citations are treated as probative of influence beyond the scholar's own circle.

Known limitations — counsel must verify. (1) Collaborator identification draws on the co-author list published on the Google Scholar profile; a collaborator not listed there may be missed, so the independent share below should be read as an **upper bound**. (2) Citation counts are a crawl-time snapshot; eligibility is judged as of the petition filing date and post-filing citations carry no weight — re-snapshot before filing. (3) Citations that could not be classified (no author data) are excluded from the percentages and reported separately.

B. Citation Independence

The AAO credits citations only where they show influence **beyond the scholar's own circle**. Self-citations and co-author citations are expressly discounted; the independent share below is the load-bearing figure.

95.7% independent of 93 classified citing papers

Citation type	Count
Independent	89
Self-citation	0
Co-author	4
Same-institution	0

3 citing papers could not be classified (no author data) and are excluded from the percentages above.

C. Significant Contributions & Their Citation Evidence

Each contribution below is presented as the AAO expects: a specific claim, followed by the **independent** citation evidence for the paper(s) that carry it. Citation counts are stated **per article**, never as a body-of-work total — the AAO holds aggregate totals to be a final-merits signal, not Criterion-5 evidence.

Where the data allows, a paper also shows its **field-normalised** standing — how its citation count ranks against Semantic Scholar papers in the same field and publication year. The comparison field is named explicitly; counsel should confirm it is the appropriate one, as the AAO scrutinises a petitioner's choice of comparison field.

Contribution 1

Claim — Contribution 1

The researcher advanced buccal drug delivery systems by synthesizing current knowledge on mucoadhesive polymers, films, and nanoparticles for small molecules and biologics.

The researcher's contribution centers on a 2023 review article titled 'Buccal delivery of small molecules and biologics: of mucoadhesive polymers, films, and nanoparticles–an update.' This work serves as the foundational piece for this line of inquiry, consolidating recent developments in non-invasive drug administration routes.

This line of work appears to address the need for comprehensive, up-to-date synthesis in the field of buccal delivery. By focusing on mucoadhesive polymers, films, and nanoparticles, the research suggests an effort to clarify the state-of-the-art for delivering both small molecules and biologics, potentially filling a gap in recent literature regarding these specific delivery mechanisms.

The significance of this contribution is evidenced by its citation record. With 74 citations, the paper has garnered attention from the scientific community. Notably, 100% of the classified citing papers originate from independent researchers, indicating that the work has been widely adopted and utilized by external scholars rather than just the researcher's immediate circle.

INDEPENDENT CITATIONS FOR THIS CONTRIBUTION: 69 · **5 flagged influential by Semantic Scholar**

CORE PAPER

Buccal delivery of small molecules and biologics: of mucoadhesive polymers, films, and nanoparticles–an update

2023 · International journal of pharmaceutics 636, 122789, 2023 · 74 citations (GS)

Field-normalised: 55 Semantic Scholar citations place it in the top 5% of Medicine papers from 2023 indexed by Semantic Scholar, by citation count.

No.	Citing paper	Citing institution(s)	Country	S2
1	Investigations on capping-induced changes in structural, optical, and thermal properties of Zn0. 96Ni0. 04S nanoparticles (2023)	—	—	—
2	Sublingual and buccal drug administration in medical emergencies (2024)	Hospital Clínic de Barcelona, Consorci Institut D'Investigacions Biomediques August Pi I Sunyer, Universitat de Barcelona, Hospital Clínic de Barcelona, Universitat de Barcelona	Spain	—
3	Mucoadhesive buccal tablets incorporating curcumin solid dispersion as a potential approach for enhancing curcumin therapeutic efficacy in oral inflammatory … (2024)	Alexandria University, Damanhour University, Pharos University in Alexandria	Egypt	—
4	Identifying the optimal dose of cannabidiol by intrabuccal administration in Kramnik (C3HeB/FeJ) mice (2025)	North-West University	South Africa	—
5	Development and In Vitro Evaluation of Aceclofenac Buccal Film (2024)	Dubai Pharmacy College for Girls, International Medical University, Universiti Malaysia Pahang Al-Sultan Abdullah	Malaysia, United Arab Emirates	—

No.	Citing paper	Citing institution(s)	Country	S2
6	DES-igning the future of drug delivery: A journey from fundamentals to drug delivery applications	—	—	—
7	Intraoral drug delivery: bridging the gap between academic research and industrial innovations	Thiomatrix Forschungs- und Beratungs GmbH, University of Innsbruck	Austria	—
8	Mucoadhesive film for oral delivery of vaccines for protection of the respiratory tract	Helmholtz Zentrum München, Technical University of Munich, Institute of Medical Microbiology and Hygiene, University of Regensburg, Ljubljana University Medical Centre	Germany, Slovenia	—
9	Mini review on the lyophilization: a basic requirement for formulation development and stability modifier	ISF College of Pharmacy	India	—
10	Smart pills and drug delivery devices enabling next generation oral dosage forms	Danish National Research Foundation, The Velux Foundations, Technical University of Denmark	Denmark	—
11	Optimized suction patch design for enhanced transbuccal macromolecular drug delivery	ETH Zurich	Switzerland	—
12	Chitosan-based buccal mucoadhesive patches to enhance the systemic bioavailability of tizanidine	Istanbul Medipol University, Istanbul University, Istanbul University-Cerrahpaşa	Turkey	—
13	Development of vancomycin, a glycopeptide antibiotic, in a suitable nanoform for oral delivery	University of Sunderland	United Kingdom	Influential
14	Optimized buccoadhesive repaglinide-loaded cubogel: In-vitro characterization and in-vivo hypoglycemic activity in a streptozotocin-induced diabetic rat ...	—	—	—
15	Tamarind seed polysaccharide-guar gum buccal films loaded with resveratrol-bovine serum albumin nanoparticles: Preparation, characterization, and ...	Southeast University, State Key Laboratory of Digital Medical Engineering, State Key Laboratory of Digital Medical Engineering, Southeast University, Zhongda Hospital Southeast University	China	—
16	Ibuprofen-Loaded, Nanocellulose-Based buccal films: the development and evaluation of promising drug delivery systems for special populations	—	—	—
17	Evaluation of Superparamagnetic Fe3O4-Ag Decorated Nanoparticles: Cytotoxicity Studies in Human Fibroblasts (HFF-1) and Breast Cancer Cells (MCF-7)	Autonomous University of Queretaro, Universidad Nacional Autónoma de México, Universidad Autónoma de Ciudad Juárez, Univer-	Mexico	—

No.	Citing paper	Citing institution(s)	Country	S2
		sidad Autónoma de Ciudad Juárez, Universidad Nacional Autónoma de México		
18	Differential enhancement of fat-soluble vitamin absorption and bioefficacy via micellization in combination with selected plant extracts in vitro	—	—	—
19	A pullulan-based bilayer film for buccal delivery of a GLP-1 peptide analogue	—	—	—
20	Fabrication and characterization of pectin films containing solid lipid nanoparticles for buccal delivery of fluconazole	Hoshi University, Silpakorn University, Thammasat University	Japan, Thailand	Background
21	Exploring new buccal films based on hydroxyethyl cellulose and Linecaps® combination for the pediatric delivery of hydrophobic molecules	—	—	—
22	A biodegradable suction patch for sustainable transbuccal peptide delivery	—	—	—
23	3D printed mucoadhesive bupropion hydrochloride buccal thin films using Liquid Crystal Display	—	—	—
24	Microneedles for oral mucosal delivery–Current trends and perspective on future directions	Guarulhos University, Pontificia Universidad Catolica de Chile, Texas Tech University	Brazil, Chile, United States	Background
25	Nanostructured Delivery Systems for Curcumin: Improving Bioavailability and Plaque-Targeting Efficacy in Atherosclerosis	—	—	**Influential**
26	3D-Printed Oral Disintegrating Films of Brain-Targeted Acetyl Salicylic Acid Nanoparticles for Enhanced CNS Delivery in Ischemic Stroke	Mercer University Health Sciences Center, Mercer University Health Sciences Center, Larkin University, Mercer University Health Sciences Center, University of California San Diego Medical Center	United States	**Influential**
27	Boosting buccal drug absorption: Mechanistic insights into bilosome-mediated delivery	Technical University of Denmark, University of Copenhagen, University of Graz	Austria, Denmark	—
28	Characteristics, preparation and applicability in oral delivery systems of cellulose ether–based buccal films	Shanghai University of Traditional Chinese Medicine	China	**Influential**
29	The assessment of pharmacokinetics and neuroprotective effect of berberine hydrochloride-embedded albumin nanoparticles via various administration routes ...	Alexandria University, Center of Excellence for Drug Preclinical Studies (CE-DPS), Pharmaceutical and Fermentation Industries Development Centre (PFIDC), City of Scientific Research and Technological Applications (SRTA-	Egypt, Saudi Arabia	—

No.	Citing paper	Citing institution(s)	Country	S2
		City), College of Pharmacy, Najran University		
30	Cannabinoid Therapies in Less-Common Disorders: Clinical Evidence and Formulation Strategies	—	—	—

Showing the 30 most-cited of 69 independent citing papers.

Independent citing papers only; self- and co-author citations excluded. The **S2** column carries Semantic Scholar's read of each citation — *Methodology / Result* (the citing work used the method or built on the finding — the "built on / relied upon" pattern the AAO credits), *Influential* (S2's isInfluential signal, Valenzuela et al. 2015), or *Background* (a passing mention).

Contribution 2

Claim — Contribution 2

The researcher developed an inhalable, excipient-free dry powder formulation of tigecycline to enable targeted treatment of pulmonary infections.

The researcher's contribution centers on the development of a novel drug delivery system, specifically an inhalable, excipient-free dry powder of tigecycline for treating pulmonary infections, as detailed in their 2023 publication. This work addresses the challenge of delivering antibiotics directly to the lungs while avoiding the potential complications associated with traditional excipients.

The originality of this approach lies in its formulation strategy, which appears to eliminate excipients to potentially improve safety or efficacy for pulmonary administration. By focusing on a dry powder format, the research suggests a practical method for localized treatment that differs from standard systemic administration routes.

The significance of this work is evidenced by its rapid uptake in the scientific community, with 14 citations recorded since 2023. Notably, all citing papers originate from independent researchers, indicating that the broader field recognizes the value and novelty of this excipient-free formulation strategy without reliance on the researcher's immediate network.

INDEPENDENT CITATIONS FOR THIS CONTRIBUTION: 12

CORE PAPER

Inhalable excipient-free dry powder of tigecycline for the treatment of pulmonary infections

2023 · Molecular Pharmaceutics 20 (9), 4640-4653, 2023 · 14 citations (GS)

No.	Citing paper	Citing institution(s)	Country	S2
1	A comprehensive review of recent advances in the applications and biosynthesis of oxalic acid from bio-derived substrates	—	—	—
2	Novel production of ultrafine particles to meet environmental and energy sustainability	Beijing Electronic Science and Technology Institute, Beijing Institute of Technology, University of Edinburgh	China, United Kingdom	—
3	Perspectives: Past, Present, and Future Developments in Particle Science and Technology	University of North Carolina at Chapel Hill	United States	—
4	AI for Product Development	—	—	—
5	Tigecycline pharmacodynamics in the hollow fiber system of Mycobacterium avium-com-	Baylor University Medical Center	United States	—

No.	Citing paper	Citing institution(s)	Country	S2
	plex lung disease and the utility of MICs and time-kill studies in drug …			
6	Modern trends in the formulation of microparticles for lung delivery using porogens: methods, principles and examples	Masaryk University	Czech Republic	Background
7	Outstanding Contributions to Aerosol Pulmonary Drug Delivery	RTI International	United States	—
8	Development of antibiotic dry powder inhalers formulations for the treatment of respiratory bacterial infections: A comprehensive review	—	—	—
9	Development and characterization of a carrier-free dry powder inhaler formulation of clarithromycin	—	—	—
10	Systematic and quantitative analyses of hollow fiber model of Mycobacterium abscessus lung disease studies and new dosing recommendations	NASOS Biotechnologies, The University of Texas at Tyler School of Medicine	United States	—
11	Systematic and quantitative analyses of hollow fiber model of Mycobacterium abscessus lung disease studies	The University of Texas at Tyler School of Medicine	United States	—
12	Innovative Dual Combination Cospray-Dried Rock Inhibitor/l-Carnitine Inhalable Dry Powder Aerosols	Florida International University, The Ohio State University College of Medicine, The University of Arizona College of Pharmacy	United States	—

Independent citing papers only; self- and co-author citations excluded. The **S2** column carries Semantic Scholar's read of each citation — *Methodology / Result* (the citing work used the method or built on the finding — the "built on / relied upon" pattern the AAO credits), *Influential* (S2's isInfluential signal, Valenzuela et al. 2015), or *Background* (a passing mention).

D. Citing-Institution Prestige & Geography

Top citing institutions

Institution	Country	World ranking	Citing papers
Romanian Academy	Romania	—	2
Carol Davila University of Medicine and Pharmacy	Romania	—	2
Mercer University Health Sciences Center	United States	—	2
Ovidius University	Romania	—	2
Universidad Autónoma de Ciudad Juárez	Mexico	—	2
Mercer University Health Sciences Center, Larkin University	United States	—	2
Alexandria University	Egypt	—	2

Institution	Country	World ranking	Citing papers
Hospital Clínic de Barcelona, Universitat de Barcelona	Spain	—	2
Mercer University Health Sciences Center, University of California San Diego Medical Center	United States	—	2
Technical University of Denmark	Denmark	SCImago #404 · THE 121 · QS 107	2
ETH Zurich	Switzerland	THE 11 · QS 7	2
Titu Maiorescu University	Romania	—	2
Universidad Autónoma de Ciudad Juárez, Universidad Nacional Autónoma de México	Mexico	—	2
Universidad del Valle de México	Mexico	—	2
University of Novi Sad	Serbia	SCImago #3069 · THE 1501+ · QS 1201-1400	2

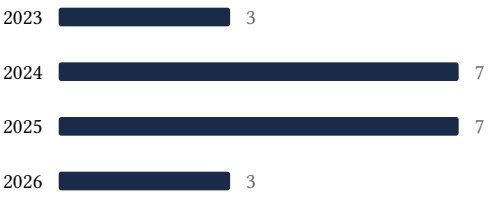
Geographic distribution of citing authors

Country	Citing papers
United States	12
India	11
China	8
United Kingdom	5
Spain	4
Denmark	3
Germany	3
Egypt	3
Chile	3
Mexico	2
Austria	2
Brazil	2

Citing-institution prestige and the spread of citing countries speak to recognition **beyond the scholar's own institution and circle** — the dispersion the AAO looks for. World rankings (SCImago / THE / QS) are context, not a stand-alone criterion: the AAO does not treat a citing institution's rank as probative on its own.

E. Citation Growth Over Time

Distinct citing papers by publication year. Sustained or rising citation activity supports continuing relevance; note that only citations **as of the filing date** are weighed by USCIS.



F. AAO Precedent Considerations

Pre-filing self-check (AAO denial patterns)

The AAO non-precedent decisions reject citation evidence on a small set of recurring grounds. Confirm the petition addresses each before filing:

- ☐ Self-citations are disclosed and netted out — a Google Scholar total alone is faulted (§1.1).
- ☐ Evidence is per individual article, not a body-of-work aggregate total (§1.2).
- ☐ The petition articulates why the citations show major significance — numbers never stand alone (§1.5).
- ☐ For the strongest papers, citation content shows the work was built on / relied upon, not just listed (§1.6, §2.2).
- ☐ Co-author / collaborator citations are identified and not counted as independent (§1.7).
- ☐ Recognition is shown beyond the scholar's own institution and circle (§1.8).
- ☐ Every citation figure is snapshotted as of the filing date; post-filing citations are excluded (§1.9).
- ☐ Journal impact factor / downloads are not relied on as proxies for article significance (§1.10, §1.12).
- ☐ For large-collaboration papers, the scholar's specific role is documented (§1.13).
- ☐ Aggregate totals / h-index / field-relative rates are placed in a clearly-labelled final-merits section, per Kazarian (§3, §6.1.7).

Disclaimer

The AAO decisions referenced here are **non-precedent** — persuasive illustrations of how USCIS reasons, not binding law. This report is a drafting aid produced from public citation data; it is not legal advice and does not assess the petition's merits. All analysis must be reviewed by qualified immigration counsel.

G. Citation Evidence Index

Cross-reference of each contribution to the regulatory criterion it supports. Counsel should map these to the petition's exhibit numbers.

Contribution	Core paper	Indep. cites	Supports
Contribution 1	Buccal delivery of small molecules and biologics: of mucoadhesive polymers, films, and nanoparticles–an update	69	8 CFR 204.5(h)(3)(v) — Criterion 5
Contribution 2	Inhalable excipient-free dry powder of tigecycline for the treatment of pulmonary infections	12	8 CFR 204.5(h)(3)(v) — Criterion 5