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**ISADORE KANFER**

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**Academic and Professional Qualifications:** B.Sc. (Pharm), B.Sc. (Hons)., Ph.D., FPS (S.A.),  
MRPharmS. (Gt.Brit)

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**Professional Background:**

Jan 2008 – present	Emeritus Professor & CIO,
Jan 2007 – present	Blanching Study Investigator
July 1999 – Dec 2006	Dean: Faculty of Pharmacy, Rhodes University
March 1999 – Dec 2006	Head: Faculty of Pharmacy, Rhodes University
April 1998 - March 1999	Vice-President, Scientific Affairs, Genpharm Inc. Toronto, Canada
May 1995 - March 1998	Director, Scientific Affairs, Genpharm Inc. Toronto, Canada
Dec 1989 - Dec 1990	Visiting Professor, School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.
1987	Director, Biopharmaceutics Research Institute, Rhodes University.
1980	Professor of Pharmaceutics, School of Pharmaceutical Sciences, Rhodes University.
July 1980 - June 1981	Visiting Professor, School of Pharmacy, University of California San Francisco, CA., USA.
Jan 1977 - June 1978	Senior Lecturer and Director of Service Laboratory, Medical School, University of Cape Town, Cape Town, South Africa.
1976 - 1979	Senior Lecturer, Rhodes University.
1969 - 1975	Lecturer, Rhodes University.
1968 - 1969	Graduate Assistant, Rhodes University.
1967	Registered Pharmacist, South Africa.
1987	Member of the Royal Pharmaceutical Society of Great Britain (MRPharm.S).
1992	Fellow of the Pharmaceutical Society of South Africa (FPS).
1994	Honorary Life Member - SA Academy of Pharmaceutical Sciences.

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**Previous Trials**

**PI/Co-Investigator** for approximately 35 bioavailability/bioequivalence studies in the period 1987 to 1995.

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**Blanching Studies for Registration**

1988 to 2006 - Approximately 6 studies for submission to the MCC for registration.

2007 – 2008 - 2 Dose-Response and Pivotal studies using chromameter assessment of blanching.

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**Topical Corticosteroid Specific Publications****A. Local Conferences**

Comparative bioavailabilities of some proprietary topical corticosteroid creams.

G.L. Coleman, J.M. Haigh and I. Kanfer.

S.A. Pharmacological Society Congress, Durban, 1976.

Abstract: S.A. Med. J., **52**, (1977) 414.

*In vivo* assessment of fluocinolone acetonide topical preparations.

G.L. Coleman, I. Kanfer and J.M. Haigh.

S.A. Pharmacological Society Congress, Potchefstroom, 1977.

Abstract: S.A. Pharm. J., **45** (1978) 451.

The effect of occlusion time on the blanching activity of betamethasone 17-valerate cream.

A.D. Magnus, I. Kanfer and J.M. Haigh.

S.A. Pharmacology Society Congress, Pretoria, 1978.

Abstract: S.A. J. Science, **75**, (1979) 322.

The effect of concentration on the ability of betamethasone 17-valerate cream to produce skin blanching.

A.D. Magnus, J.M. Haigh and I. Kanfer.

S.A. Pharmacology Society Congress, Pretoria, 1978.

Abstract: S.A. J. Science, **75**, (1979) 322.

Aspects of the bioavailability of topical corticosteroid formulations.

G.L. Coleman, J.M. Haigh and I. Kanfer.

Academy of Pharmaceutical Sciences Conference, Grahamstown, 1980.

Abstract: S.A. Pharm. J., **47**, (1980) 244.

Stability of betamethasone 17-valerate in semi-solid dosage forms.

A.D. Magnus, J.M. Haigh and I. Kanfer.

Academy of Pharmaceutical Sciences Conference, Grahamstown, 1980.

Abstract: S.A. Pharm. J., **47**, (1980) 249.

Comparative blanching activities of some topical corticosteroid-containing lotions.

E. Meyer, I. Kanfer and J.M. Haigh.

Academy of Pharmaceutical Sciences Conference, Durban, 1981.

Abstract: S.A. Pharm. J., **48**, (1981) 224.

Comparative bioavailability of some locally manufactured betamethasone valerate containing preparations.

E. Meyer, J.M. Haigh and I. Kanfer.

Academy of Pharmaceutical Sciences Congress, Port Elizabeth, 1982.

Abstract: S.A. Pharm. J., **49**, (1982) 218.

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The effect of urea on the release rate of betamethasone 17-valerate from topical creams.  
J.G. Horrocks, E. Meyer, J.M. Haigh and I. Kanfer.  
Academy of Pharmaceutical Sciences Congress, Potchefstroom, 1983.  
Abstract: S.A. Pharm. J., **50**, (1983) 149.

Bioequivalence assessment of oral sustained release dosage forms: Application of the Bioequivalence Factor.  
R. Dowse and I. Kanfer.  
Academy of Pharmaceutical Sciences Congress, Pretoria, 1985.  
Abstract: S.A. Pharm. J., **52**, (1985) 115.

The relative potency of two new locally available topical corticosteroid creams.  
E. Meyer, E.W. Smith, J.M. Haigh and I. Kanfer.  
Academy of Pharmaceutical Sciences Congress, Pretoria, 1985.  
Abstract: S.A. Pharm. J., **52**, (1985) 120.

A comparison of the blanching activities of commercial fluocinolone acetonide lotions from three different countries.  
E. Meyer, E.W. Smith, J.M. Haigh and I. Kanfer.  
Academy of Pharmaceutical Sciences Congress, Cape Town, 1986.  
Abstract: S.A. Pharm. J., **53**, (1986) 78.

Differences in blanching response to topical corticosteroids on different areas of the human forearm.  
J.M. Haigh, I. Kanfer, E. Meyer and E.W. Smith.  
Academy of Pharmaceutical Sciences Conference, Grahamstown, 1987.  
Abstract: S.A. Pharm. J., **54**, (1987) 82.

A comparison of the blanching activities of Dermovate, Betnovate and Eumovate creams.  
E. Meyer, J.M. Haigh and I. Kanfer.  
Academy of Pharmaceutical Sciences Conference, Grahamstown, 1987.  
Abstract: S.A. Pharm. J., **54**, (1987) 83.

The reproducibility of the human skin blanching assay.  
E. Meyer, E.W. Smith, J.M. Haigh and I. Kanfer.  
Academy of Pharmaceutical Sciences Conference, Sun City, 1989.

Pharmacodynamic modelling of corticosteroid-induced-skin blanching from two pilot studies.  
M.P. Demana, E.W. Smith, J.M. Haigh, R.B. Walker, L.H. Purdon and I. Kanfer.  
17th Congress of the Academy of Pharmaceutical Sciences, Midrand, 1996.

Bioequivalence Assessment of Topical Corticosteroid Formulations:  
Chromametric Studies.  
B V Chamboko, MS Skinner and I Kanfer  
Academy of Pharmaceutical Sciences Congress, Grahamstown, 2004

Evaluation of dose duration-response for a topical corticosteroid cream containing clobetasol 17 – propionate  
Wai Ling Au, Michael Skinner and Isadore Kanfer  
27<sup>th</sup> Academy of Pharmaceutical Sciences Congress, 4<sup>th</sup> ICPPS Conference, Vanderbijlpark 2006

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Application of microdialysis for the assessment of bioequivalence of ketoprofen topical formulations

Ralph Nii Okai Tettley-Amlalo and Isadore Kanfer

27<sup>th</sup> Academy of Pharmaceutical Sciences Congress, 4<sup>th</sup> ICPPS Conference, Vanderbijlpark 2006

Comparison of visual and chromameter methods for the assessment of bioequivalence of topical corticosteroid products

Wai Ling Au, Michael F. Skinner and Isadore Kanfer

28<sup>th</sup> Academy of Pharmaceutical Sciences Congress, Langebaan, September 2007

Correlation of the Human Skin Blanching Assay with Tape Stripping Methodology for the Assessment of Bioequivalence of Topical Products

Wai Ling Au, Michael F. Skinner, Isadore Kanfer

29<sup>th</sup> Academy of Pharmaceutical Sciences Congress, Hunters Retreat, Rustenberg, September 2008

Bioequivalence Testing Using the Tape Stripping Technique

Wai Ling Au, Michael F. Skinner and Isadore Kanfer

S.A. Pharmacological Society Congress, Grahamstown, 2008

Bioequivalence Assessment Of Topical Dosage Forms Using Microdialysis

Ralph Tettley-Amlalo, Mike Skinner, Roger Verbeeck, Isadore Kanfer

29<sup>th</sup> Academy of Pharmaceutical Sciences Congress, Hunters Retreat, Rustenberg, September 2008

Determination of Clotrimazole in Human Skin by Tape Stripping Following Topical Application of a Cream Formulation.

Natalie R. Parfitt, Isadore Kanfer

S.A. Pharmacological Society Congress, Grahamstown, 2008

and presented at the MRC Research Day, SA Medical Research Council, Cape Town, 16/17 October, 2008

**B. International Conferences**

A comparison of the blanching activities of commercial betamethasone 17-valerate preparations from three countries.

J.M. Haigh, E. Meyer, E.W. Smith and I. Kanfer.

Pharmacy World Congress '91, Washington DC, USA.

Abstract: Int. Pharm. J., **5** (Suppl.) cs 97, 1991.

An assessment of some variables affecting the Human Skin Blanching Assay.

E. Meyer, J.M. Haigh, E.W. Smith and I. Kanfer.

Pharmacy World Congress '91, Washington DC, USA.

Abstract: Int. Pharm. J., **5**, (Suppl.) cs 97, 1991.

Comparison of Tape Stripping and the Human Skin Blanching Assay for the Assessment of the Bioequivalence of Topical Clobetasol Propionate Formulations

Wai Ling Au, Michael F. Skinner, Isadore Kanfer

Presented at the American Association of Pharmaceutical Scientists Conference Annual Meeting and Exposition, Los Angeles, USA

November 8-12, 2009

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**INVITED LECTURES:**

**Keynote Lecture:** *'Bioequivalence of Topical Dosage Forms Intended for Local Action'*, International Symposium On State Of Pharmaceutical Research And Development In Canada And Bioequivalence Of Drug Products With Special Characteristics

**Chairman Of Session 2:** sponsored by the Canadian Society for Pharmaceutical Sciences, held in Ottawa, Ontario, Canada, February 13-14, 1998.

**Keynote Lecture:** 'Bioequivalence assessment of drugs not intended to be absorbed into the systemic circulation', September 2000, South African Academy of Pharmaceutical Sciences 21<sup>st</sup> Annual Congress, Grahamstown, South Africa.

**Keynote Lecture:** 'Bioequivalence Assessment of Dosage Forms not Intended to be Absorbed into the Systemic Circulation', 9 March, 2005  
SFBC/ANAPHARM SYMPOSIUM  
Developing Topical Generic Products – Roadmap to Success  
Hilton Hotel, New Brunswick, NJ, USA.

**Keynote Lecture:** 'Similarities and Differences in International Bioequivalence Requirements between Different Countries', 10 March, 2005  
SFBC/ANAPHARM SYMPOSIUM  
Oral Generic Drug Development – Key Information for Decision Makers  
Hilton Hotel, New Brunswick, NJ, USA.

Bioequivalence Assessment of Topical Dermatological Dosage Forms: "Official" and Investigative Methods  
12th Canadian Society for Pharmaceutical Sciences (CSPS) Annual Meeting , Toronto, Canada  
June 6, 2009

**Publications - Journals**

Comparative blanching activities of proprietary diflucortolone valerate topical preparations.  
G.L. Coleman, I. Kanfer and J.M. Haigh.  
*Dermatologica*, **15**, (1978) 224-230.

Comparative blanching activities of locally manufactured proprietary fluocinolone acetonide topical preparations.  
G.L. Coleman, A.D. Magnus, J.M. Haigh and I. Kanfer.  
*S.A. Med. J.*, **56**, (1979) 447-449.

Assessment of some variables affecting the blanching activity of betamethasone 17-valerate cream.  
A.D. Magnus, J.M. Haigh and I. Kanfer.  
*Dermatologica*, **160**, (1980) 321-327.

The release of betamethasone 17-valerate from extemporaneous dilutions of a proprietary topical cream.  
A.D. Magnus, J.M. Haigh and I. Kanfer.  
*Dermatologica*, **163**, (1981) 331-337.

Comparative blanching activities of some topical corticosteroid containing lotions.  
E. Meyer, I. Kanfer and J.M. Haigh.  
*S.A. Pharm. Journal*. **48**, (1981) 551-552.

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Comparative bioavailability of some locally manufactured betamethasone valerate containing preparations.

E. Meyer, J.M. Haigh and I. Kanfer.  
S.A. Pharm. J., **50** (1983) 445-447.

A stability-indicating HPLC assay with on-line clean-up for betamethasone 17-valerate in topical dosage forms.

E.W. Smith, J.M. Haigh and I. Kanfer.  
Int. J. Pharm., **27**, (1985) 185-192.

Comparison of blanching activities of Dermovate, Betnovate and Eumovate creams and ointments.

E. Meyer, A.D. Magnus, J.M. Haigh and I. Kanfer.  
Int.J.Pharm., **48**, (1988) 63-66.

Potency ranking of two new topical corticosteroid creams containing 0.1% desonide or 0.5% halometasone, utilizing the human skin blanching assay.

E. Meyer, E.W. Smith, J.M. Haigh and I. Kanfer.  
Arzneim.Forsch., **38**, (1988) 1840-1843.

Evaluation of the proposed FDA pilot-dose response methodology for topical corticosteroid bioequivalence testing.

P.H. Demana, E.W. Smith, R.B. Walker, J.M. Haigh and I. Kanfer.  
Pharm.Res. **14**, (1997) 303-307.

The human skin blanching assay for in vivo topical corticosteroid assessment.

I. Reproducibility of the Assay.

John M. Haigh, Eric Meyer, Eric W. Smith and Isadore Kanfer.  
Int.J.Pharm. **152** (1997) 179-183.

The human skin blanching assay for in vivo topical corticosteroid assessment.

II. Subject- and observer-dependent variation in blanching responses.

John M. Haigh, Eric Meyer, Eric W. Smith and Isadore Kanfer.  
Int.J.Pharm. **152** (1997) 185-192.

Bioequivalence Assessment Of Topical Clobetasol Propionate Products Using Visual And Chromametric Assessment Of Skin Blanching

Wai Ling Au, Michael Skinner, Isadore Kanfer

J Pharm Pharmaceut Sci ([www.cspcsCanada.org](http://www.cspcsCanada.org)) **11** (1), (2008), 160-166.

Application of dermal microdialysis for the evaluation of bioequivalence of a ketoprofen topical gel

Ralph N Tettey-Amlalo, Isadore Kanfer, Michael F Skinner, Eva M Benfeldt, Roger K Verbeeck

Eur. J. Pharm Sci., **36**, (2009), 219-225.

Comparison of Tape Stripping with the Human Skin Blanching Assay for the Bioequivalence Assessment of Topical Clobetasol Propionate Formulations

Wai Ling Au, Michael Skinner and Isadore Kanfer

J Pharm Pharmaceut Sci., *In Press*

### Book Chapter:

Assessment of Topical Dosage Forms Intended for Local or Regional Activity

Isadore Kanfer, Ralph Nii Okai Tettey-Amlalo, Wai Ling Au and Betsey Hughes-Formella

In "Generic Drug Product Development: Specialty Drug Products"  
Chapter 4, January 2010, *Informa Healthcare*, New York, London

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**Other Articles, Letters and Proceedings**

Relative potencies of topical steroid formulations.  
J.M. Haigh, I. Kanfer, E. Meyer and E. Smith.  
Br. J. Derm., **85**, (1985) 502-503.

The human skin blanching assay - uses and abuses.  
J.M. Haigh, I. Kanfer, E. Meyer and E.W. Smith.  
Br. J. Derm., **114**, (1986) 637-638.

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**Invited Reviews**

Assessment of topical corticosteroid preparations: The human skin blanching assay.  
J.M. Haigh and I. Kanfer.  
International Journal of Pharmaceutics, Volume **19**, 245-262, 1984.