



## Curriculum Vitae

Personal information **Ivica Malnar**

### Work experience

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1. Employer: Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
  - Start date: 122019
  - End date: present
  - Position: Senior Pharmaceutical Officer for Documentation Assessment
  - Activities: quality assessment of dossiers for human medicines containing chemical active substances in national, decentralized and centralized procedures (marketing authorization/variation applications and scientific advice, covering active substances made by chemical synthesis and medicinal products with different routes of administration - oral, parenteral, topical)
  - Country: Croatia
2. Employer: Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
  - Start date: 102016
  - End date: 122019
  - Position: Principal Advisor for Documentation Assessment
  - Activities: quality assessment of dossiers for human medicines containing chemical active substances in national, decentralized and centralized procedures (marketing authorization/variation applications and scientific advice, covering active substances made by chemical synthesis and medicinal products with different routes of administration - oral, parenteral, topical)
  - Country: Croatia
3. Employer: Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
  - Start date: 052012
  - End date: 092016
  - Position: Senior Advisor – Specialist for Quality Assessment
  - Activities: quality assessment of dossiers for marketing authorization/variation applications for human medicines containing chemical active substances in national, decentralized and centralized procedures (covering active substances made by chemical synthesis and medicinal products with different routes of administration - oral, parenteral, topical)
  - Country: Croatia
4. Employer: Galapagos Research Centre Ltd, Zagreb, Croatia
  - Start date: 092010
  - End date: 052012
  - Position: Group Leader
  - Activities: project leader of anti\_inflammatory programme in lead identification/lead optimization phase
  - Country: Croatia
5. Employer: GlaxoSmithKline Research Centre Zagreb Ltd, Zagreb, Croatia
  - Start date: 042006
  - End date: 092010
  - Position: Team Leader
  - Activities: project leader of basic research programme (PK Behaviour, Target Identification and Mode of Action) as well as several programmes in lead identification/lead optimization phase in various therapeutic areas (inflammation, cardiovascular, oncology)
  - Country: Croatia
6. Employer: PLIVA – Research Institute Ltd, Zagreb, Croatia
  - Start date: 122000
  - End date: 042006
  - Position: Senior Scientist – Specialist for chemical synthesis
  - Activities: synthetic organic chemistry, medicinal chemistry (Target Identification, Hit to Lead and Lead Optimization)
  - Country: Croatia
7. Employer: School of Pharmacy, University of Wisconsin – Madison, WI, USA
  - Start date: 011998
  - End date: 121999
  - Position: Research Associate / Postdoctoral Fellow
  - Activities: scientific research - postdoctoral research on enzymatic oxidative phenolic coupling reactions
  - Country: USA
8. Employer: Faculty of Pharmacy and Biochemistry University of Zagreb
  - Start date: 021990
  - End date: 122000
  - Position: Research Scientist / Assistant
  - Activities: scientific research - working on M.Sc. and Ph.D. Theses (biomimetic polyene cyclization reactions)
  - Country: Croatia

### Education and training

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#### Education

1. Faculty of Pharmacy and Biochemistry University of Zagreb
  - Start date: 041993

- End date: 121997
  - Qualification: Ph.D. (Chemistry)
  - Country: Croatia
2. Faculty of Science and Mathematics University of Zagreb
    - Start date: 021990
    - End date: 031993
    - Qualification: M.Sc. (Chemistry / Theoretical and physical organic chemistry)
    - Country: Croatia
  3. Faculty of Pharmacy and Biochemistry University of Zagreb
    - Start date: 101985
    - End date: 011990
    - Qualification: M.Pharm. (Pharmacy)
    - Country: Croatia

#### Training

1. Subject: Impurity control in the European Pharmacopoeia
  - Date: 6 May 2021
  - Organizer: EDQM Council of Europe
  - Virtual course
2. Subject: Practical Management of Impurities and Development of Effective and Comprehensive Control Strategies
  - Date: 16-24 Mar 2021
  - Organizer: Scientific Update
  - Virtual course
3. Subject: Overview of the Guidance for Industry: Control of Nitrosamine Impurities in Human Drugs
  - Date: 2 Oct 2020
  - Organizer: FDA
  - Webinar
4. Subject: ICH Q12 - Life Cycle Management
  - Date: 5 Nov 2019
  - Organizer: ECA
  - Webinar
5. Subject: ICH Q8 and Q11 Training Course
  - Date: 10-11 April 2019
  - Organizer: ECA
  - Hamburg, Germany
6. Subject: The next generation pharma skills you will need in view of continuous manufacturing
  - Date: 11-13 Sep 2018
  - Organizer: Ghent University and AM-TEAM
  - Binzen, Germany
7. Subject: Nano and Micro Formulations
  - Date: 13-14 Mar 2018
  - Organizer: ECA
  - Berlin, Germany
8. Subject: Impurities Forum Part I and II
  - Date: 27-29 Jun 2017
  - Organizer: ECA
  - Copenhagen, Denmark
9. Subject: The Place of the Certification Procedure in the Global Regulatory Environment
  - Date: 19-20 Sep 2017
  - Organizer: EDQM
  - Prague, Czech Republic
10. Subject: Pharmaceutical Packaging Systems Part 1 and Part 2
  - Date: 7-9 Jun 2016
  - Organizer: ECA
  - Hamburg, Germany
11. Subject: HMA/EMA - Training on Quality Assessment of Drug Substances
  - Start date: 12-13 Oct 2015
  - Organiser: Estonian State Agency of Medicines and the EU Network Training Centre
  - Tallin, Estonia
12. Subject: Genotoxic Impurities
  - Start date: 9-11 Jun 2015
  - Organiser: Informa Life Sciences
  - London, UK
13. Subject: PTI - Genotoxic Impurities
  - Date: 14-15 May 2014
  - Organiser: PTI
  - London, UK
14. Subject: ECA - Setting Specifications
  - Date: 20-21 Nov 2013
  - Organiser: ECA
  - Barcelona, Spain

## Additional information

### Publications

- 1) I. Malnar, O. Kronja, K. Humski, and S. Borčić: "Solvolysis Kinetics of 1-Chloro-1-phenyl-5,9,14,18,22-pentamethyl-5,9,13,17,21-tricosapentaene, a Squalene Derivative. Indication of Participation" *Croat. Chem. Acta* 65 (1992) 547\_549.
- 2) S. Borčić, K. Humski, O. Kronja, and I. Malnar: "Extended  $\square$ -Participation in Biomimetic Cyclization of Squalene Derivatives" *Croat. Chem. Acta* 69 (1996) 1347\_1359.
- 3) M. Keča, S. Gross, I. Malnar, Z. Kalodera, and R. Malojčić: "Isolation of solanesol from tobacco (*Nicotiana tabacum* L.) by the procedure of classical extraction and extraction by ultrasound" *Farm. Glas.* 53 (1997) 173\_182. (in Croatian)
- 4) I. Malnar, K. Humski, and O. Kronja: "Hammett  $\square$ + Values as Kinetic Evidence for the Concerted Biomimetic Bicyclization Mechanism" *J. Org. Chem.* 63 (1998) 3041\_3044.
- 5) I. Malnar and O. Kronja: "A Case of Concerted Formation of Five and Six Member Rings; Solvolytic Behavior of 1-Aryl-1-chloro-4,8,13,17,21-pentamethyl-4,8,12,16,20-docosapentaenes" *Croat. Chem. Acta* 72 (1999) 115\_121.
- 6) I. Malnar and C. J. Sih: "Synthesis of the bis-diaryl ether fragment of vancomycin via enzymatic oxidative phenolic coupling" *Tetrahedron Lett.* 41 (2000) 1907\_1911.

- 7) I. Malnar and C. J. Sih: "Chloroperoxidase\_catalyzed chlorination of didechloroagluovancomycin and vancomycin" J. Mol. Catal. B: Enzymatic 10 (2000) 545\_549.
- 8) C. J. Sih and I. Malnar: "Peroxidase\_catalyzed oxidative phenolic coupling of some tripeptides containing tyrosine and hydroxyphenylglycine residues" Biocatalysis and Biotransformation 18 (2000) 301\_310.
- 9) Zrinka Banić Tomišić, Andreja Čempuh, and Ivica Malnar: "7\_Cyclopentyl\_5\_(4\_phenoxyphenyl)\_7H\_pyrrolo[2,3\_d]pyrimidine\_4\_yl\_amine, an Lck Tyrosine Kinase Inhibitor" Acta Cryst. E57 (2001) 0511\_0513.
- 10) I. Malnar, S. Jurić, V. Vrček, Ž. Gjuranović, Z. Mihalić, and O. Kronja: "Solvolysis of 1,1\_Dimethyl\_4\_Alkenyl Chlorides; Evidence for  $\pi$  Participation" J. Org. Chem. 67 (2002) 1490\_1495.
- 11) S. Dragojević, V. Šunjić, V. Bencetić\_Mihaljević, J. Ralić, M. Mesić, I.J. Elenkov, A. Filipović Sučić, A. Čempuh Klunkay, L. Lerman, M. Ilijaš, V. Gabelica\_Marković, I. Malnar: "Determination of aqueous stability and degradation products of series of coumarin dimers" J. Pharm. Biomed. Anal. 54 (2011) 37\_47.
- 12) V. Stepanić, S. Koštrun, I. Malnar, M. Hlevnjak, K. Butković, I. Čaleta, M. Dukšić, G. Kragol, O. Makaruha\_Stegić, L. Mikac, J. Ralić, I. Tatić, B. Tavčar, K. Valko, S. Zulfikari, V. Munić: "Modeling Cellular Pharmacokinetics of 14\_ and 15\_ Membered Macrolides with Physicochemical Properties" J. Med. Chem. 54 (2011) 719\_733.
- 13) K. Nujić, M. Smith, M. Lee, D. Belamarić, L. Tomašković, S. Alihodžić, I. Malnar, D. Polančec, K. Schneider, V. Eraković Haber: "Valosin containing protein (VSP) interacts with macrolide antibiotics without mediating their anti\_inflammatory activities" Eur. J. Pharmacol. 677 (2012) 163\_172.
- 14) I. Čaleta, A. Čikoš, D. Žiher, I. Đilović, M. Dukšić, D. Gembarovski, I. Grgičević, M. Bukvić Krajačić, D. Filić, D. Matković\_Čalogović, I. Malnar, S. Alihodžić: "Synthesis, NMR and X\_ray structure analysis of macrolide aglycons" Struct. Chem. 23 (2012) 1785\_1796.
- 15) Marina Ilijaš, Ivica Malnar, Vesna Gabelica Marković, Višnja Stepanić: "Study of lipophilicity and membrane partition of 4\_hydroxycoumarins by HPLC and PCA" J. Pharm. Biomed. Anal. 76 (2013) 104\_111.
- 16) Ivaylo Jivkov Elenkov, Boška Hrvčić, Stribor Marković, Milan Mesić, Andreja Čempuh Klunkay, Lidija Lerman, Anita Filipović Sučić, Ines Vujasinović, Berislav Bošnjak, Karmen Brajša, Dinko Žiher, Nada Košutić Hulita, Ivica Malnar: "Synthesis and Anti\_inflammatory Activity of Novel Furochromenes" Croat. Chem. Acta 86 (2013) 253\_264.
- 17) Astrid Milić, Vlatka Bencetić Mihaljević, Jovica Ralić, Ana Bokulić, Danijela Nožinić, Branka Tavčar, Boris Mildner, Vesna Munić, Ivica Malnar, Jasna Padovan: "A comparison of in vitro ADME properties and pharmacokinetics of azithromycin and selected 15\_membered ring macrolides in rodents" Eur. J. Drug Metab. Pharmacokin. 39 (2014) 263\_276.
- 18) Ana Čikoš, Irena Čaleta, Dinko Žiher, Mark B. Vine, Ivaylo J. Elenkov, Marko Dukšić, Dubravka Gembarovski, Marina Ilijaš, Snježana Dragojević, Ivica Malnar, Sulejman Alihodžić: "Structure and conformational analysis of spiroketals from 6\_O\_methyl\_9(E)\_hydroxyiminoerythronolide A" Beilstein J. Org. Chem. 11 (2015) 1447\_1457.
- 19) Sanja Koštrun, Vesna Munić Kos, Maja Matanović Škugor, Ivana Palej Jakopović, Ivica Malnar, Snježana Dragojević, Jovica Ralić, Sulejman Alihodžić: "Around the macrolide \_ Impact of 3D structure of macrocycles on lipophilicity and cellular accumulation" Eur. J. Med. Chem. 133 (2017) 351\_364.

## Projects

EU Twinning Project "Support to the Institute for Medicines and Medical Devices of Montenegro (CInMED)", January 2021 - July 2022, training on quality assessment

## Memberships

Croatian Pharmaceutical Society, 1996 – present

Croatian Chemical Society, 1990 – present (Medicinal Chemistry Section Head, 2009 – 2012; European Federation for Medicinal Chemistry, Council Member, 2010 – 2012)

American Chemical Society, 2004 – 2021

## Other Relevant Information

EMA Quality Working Party (QWP) member, 2021 - present

The EC, Europe Topic Leader in ICH M4Q(R2) EWG, 2024 - present

The EC, Europe Deputy Topic Leader (Quality representative) in ICH Q3C EWG, 2021 - present

EDQM AdHoc committee member, 2020 - present

EDQM Chemical Technical Advisory Board (chemical TAB) member, 2018 - 2024

EDQM External assessor in the Certification procedure, 2016 - present

Experience in preparation and delivery of training or other educational activities

Mentor of 3 Ph.D. theses and 1 postgraduate specialist thesis

> 20 years of experience in synthetic organic and medicinal/pharmaceutical chemistry

14 years of regulatory experience as quality assessor