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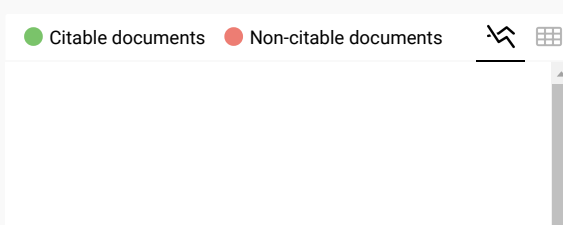
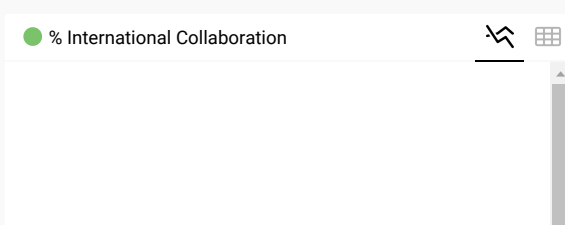
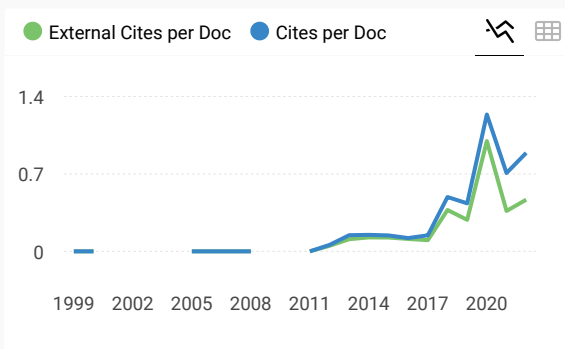
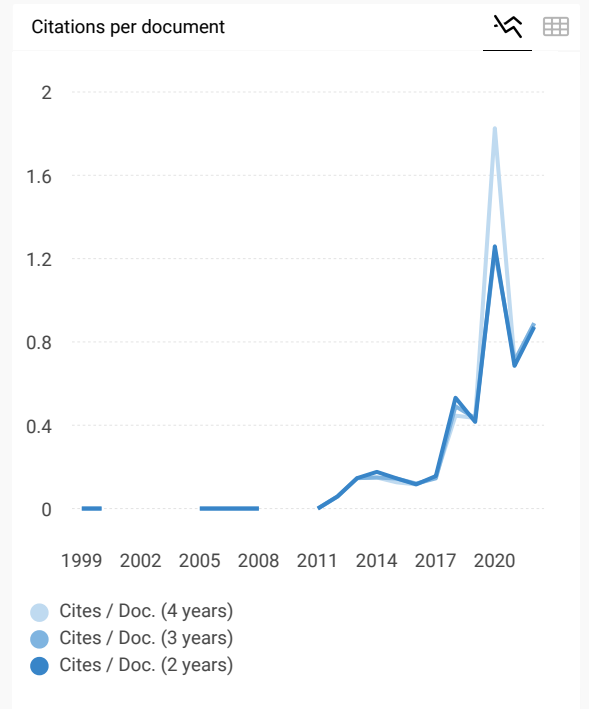
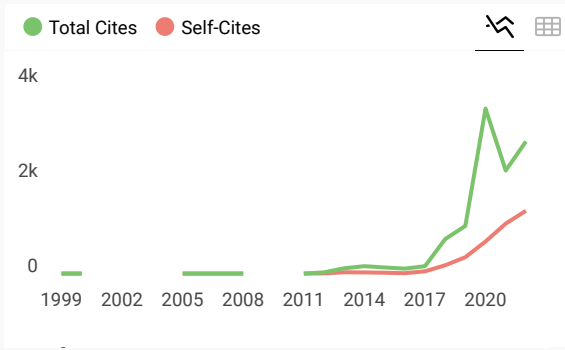
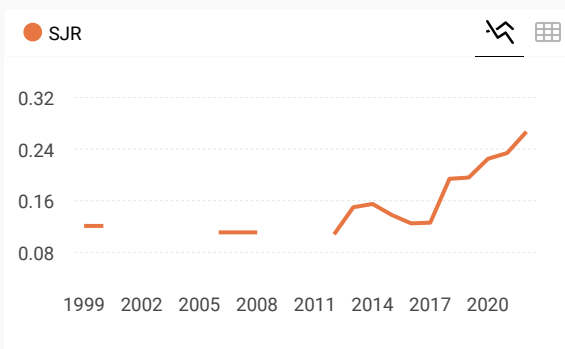
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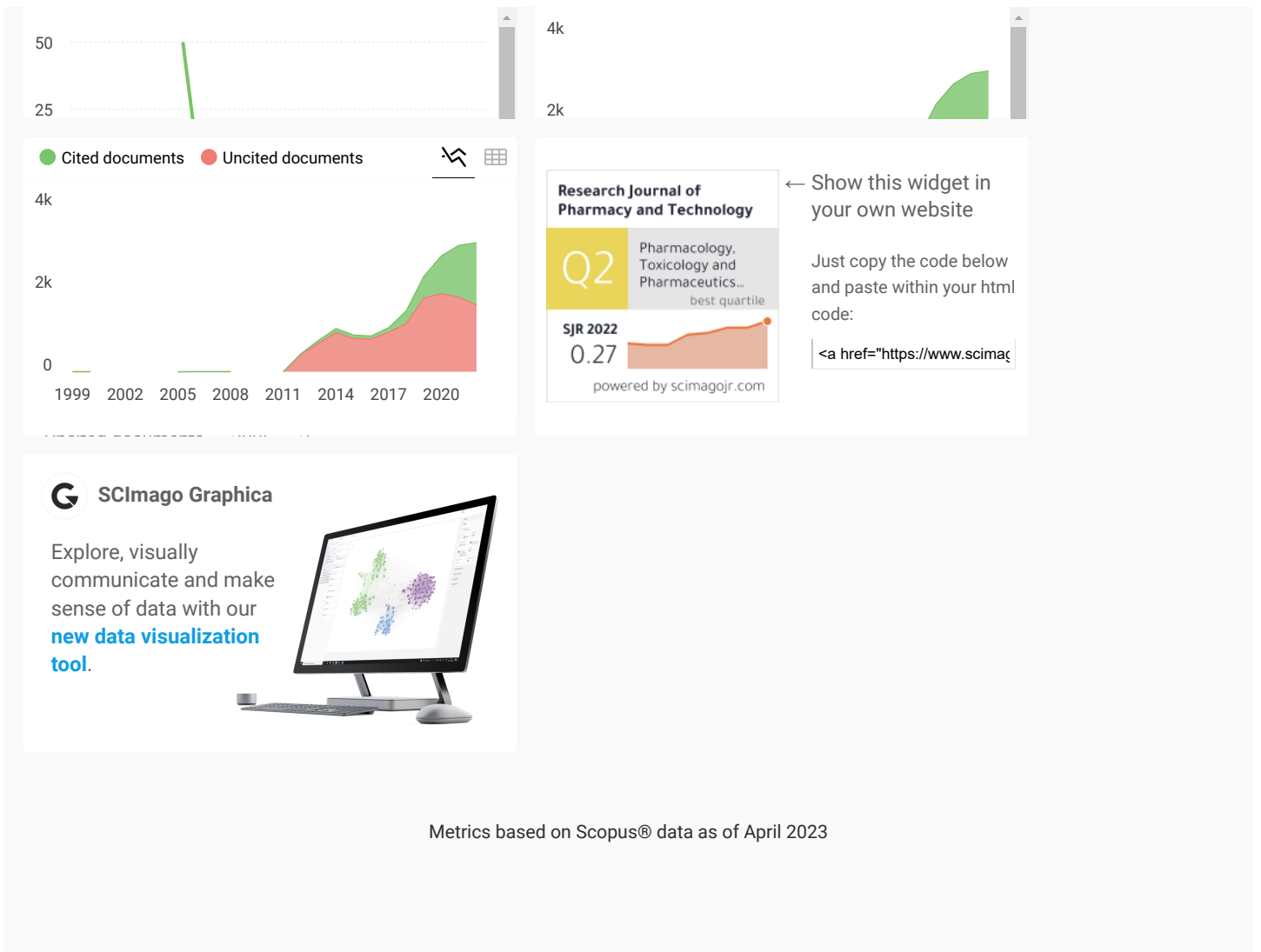
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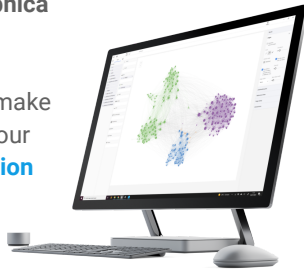
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DR. ASHOK A. HAJARE ()
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SANYAM GANDHI ()
International Regulatory Strategy Lead Takeda Pharmaceutical Company Ltd., 1 Kingdon St., Paddinton, London, W2 6BD England
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PRAVEEN KUMAR SHARMA ()
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DR SUDIIP KUMAR MANDAL ()
Dr. B. C. Roy College of Pharmacy & Allied Health Sciences, Durgapur, West Bengal, India
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Dr.K.Manikandan, M.Pharm., Ph.D., Associate Professor, SRM College of Pharmacy, SRM University, Kattankulathur, Kancheepuram - 603203 Mobile Number - 0 9444708710
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MOUSHIRA ZAKI ()
 El Bhouth ST.
 Email: moushiraz@yahoo.com
 Home Page ()



DR. AMIT KUMAR CHATURVEDI ()
 Department Of Chemistry, J.S.University, Shikohabad (U.P.)
 Email: achaturvedi794@gmail.com
 Home Page ()



DR. MANOJ KUMAR JENA ()
 Department of Biotechnology, School of Bioengineering and Biosciences, Lovely Professional University, Phagwara-144411, Punjab, India
 Email: manoj_20283@lpu.co.in
 Home Page ()

AVINASH BABURAO THALKARI ()
 Vasant Pharmacy College Kaij Affiliated by MSBTE Mumbai



AVINASH THALKARI ()
 Email: avinashthalkari@rediffmail.com
 Home Page ()



RAJESH L. DUMPALA ()
 Alembic Pharma Campus, Alembic Rd, Subhanpura, Vadodara, Gujarat 390003
 Email: rdumpala64@gmail.com
 Home Page ()



ABDULRAHMAN R. MAHMOOD ()
 *Department of Chemistry, College of Education for Pure Sciences/(Ibn-Al-Haitham), University of Baghdad, Baghdad, Iraq.
 Email: abdulrahman.r.m@ihcoedu.uobaghdad.edu.iq
 Home Page ()



DR. T.C. VENKATESWARULU ()
 Department of Bio-Technology, Vignan's Foundation for Science, Technology & Research, Vadlamudi-522213, Andhra Pradesh
 Email: venki_biotech327@yahoo.com
 Home Page ()



DR. PRASHANT L. PINGALE ()
 Associate Professor of Pharmaceutics, GE'S Sir Dr. M. S. Gosavi College of Pharmaceutical Education and Research, Nashik-422005, Maharashtra, India
 Email: prashantpingale@gmail.com
 Home Page ()



DR. GURVINDER SINGH ()
 School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab
 Email: guri_ph@yahoo.co.in
 Home Page ()



DR. SUSHANT KUMAR ()
 UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCES, SAIFAL ETWAH, UTTAR PRADESH
 Email: K.SUSHANT25@GMAIL.COM
 Home Page ()



MR. PARESH ASHOK PATIL ()
 Jay ambe Nivas Gujar galli, Shahada Dist-Nandurbar
 Email: rcp.paresapatil@gmail.com
 Home Page ()



VAMSKRISHAN BIRUPANENI ()
 4401 manchester avenue, Apt#53, CA, 95207.
 Email: vamskrishan99@gmail.com
 Home Page ()



DR. SUNIL KUMAR ()
 122 Ground Floor Research Block A Post Graduate Institute of Medical education and Research
 Email: drsunilkumarjaswal@gmail.com
 Home Page ()



SANDEEP PODDAR ()
 Lincoln University College, Wisma Lincoln, No. 12-18, Off Jalan Perbandaran, SS6/12 Kelana Jaya, Selangor D. E., Malaysia
 Email: sandeepoddar@lincoln.edu.my
 Home Page ()



DR. ZAKIR HUSSAIN ()
 Dr.Zakir Hussain S/o MD.LUNUS Rtd Express mail guard SCRLY Near mohammadia masjid, Satyanarayana pet GUNTAKAL-515801 ANANTAPUR DIST ANDHRA PRADESH-INDIA
 Email: zakirhussains765@gmail.com
 Home Page ()



BASIL A. ABBAS ()
 University of Basrah, Basrah, Iraq
 Email: basil.abbas@uobasrah.edu.iq
 Home Page ()



DR. V. PALANISINGH ()
 Pudukkottai, Ulagampatti post Sivagangai Dist, Tamil Nadu PIN 630410
 Email: vpalanisinh@gmail.com
 Home Page ()



NASIR MUJFAQ YOUNIS ()
 University of Mosul, College of Nursing
 Email: nasir.mujfaq@uomosul.edu.iq
 Home Page ()



SANDIP SEN ()
 SRIKRUPA INSITUTE OF PHARMACEUTICAL SCIENCES, VELIKATTA, KONDAPKKA, SIDDIPET-502277
 Email: sandipen2010@gmail.com
 Home Page ()

**DR. BISWA MOHAN SAHOO** ()

Roland Institute of Pharmaceutical Sciences (Biju Patnaik University of Technology Nodal Centre of Research) Berhampur-760010, Odisha, India
 Email: drbiswamohansahoo@gmail.com
 Home Page ()

**DR.MATADEEN BHARTI** ()

Department of Fluorosis Chief Medical and Health Officer Dhar MP India pin code 454001
 Email: drmdbharti@gmail.com
 Home Page ()

**DR.PRASENJIT MONDAL** ()

Vaageswari institute of Pharmaceutical Sciences, Ramakrishna colony, Karimnagar, Telangana, India
 Email: prasenjitmyname@gmail.com
 Home Page ()

**DR.ANJU THAWARE** ()

Associate professor, Dept of samhita Siddhant ,MGACRCH,salod wardha ,(DMIMSU,wardha) Maharashtra ,India
 Email: anju.samhita@dmimsu.edu.in
 Home Page (https://mgachrc.org/departments)

**DR. NITIN SHARMA** ()

Department of Biotechnology Chandigarh Group of Colleges, Landran, Mohali- 140307
 Email: nitin.3994@cgcc.edu.in
 Home Page (https://www.cgcc.edu.in/chandigarh-college-of-technology)

**PROF. GALLA RAJITHA** ()

Prof. G. Rajitha, Professor, Institute of Pharmaceutical Technology, Sri Padmavati Mahila Visvavidyalayam, Tirupati - 517502, Andhra Pradesh, India
 Email: rajitha.galla@gmail.com
 Home Page (http://www.spmv.ac.in/)

**ASHISH GUPTA** ()

Flat no.E113,Nariman Point, Mahalaxmi Nagar Indore MP
 Email: ashishgupta@acropolis.edu.in
 Home Page (www.acropolis.in)

HUSAM AL-HRAISHAWI ()<https://www.rjptonline.org/EditorialBoard.aspx>

17/46



195 Little Albany St.
 Email: hra10@scarletmail.rutgers.edu
 Home Page (https://uomisan.edu.iq/ar/)

**TUHING SARKAR** ()

Jakir Hossain Institute of Pharmacy, VIII. & PO- Miapur, Dist- Murshidabad, Pin: 742225, West Bengal.
 Email: gantuhin@gmail.com
 Home Page (http://www.jhip-india.co/)

**BHUPENDRA G. PRAJAPATI** ()

Gangpat Vidyasagar, Mahesna 384012
 Email: bhupen27@gmail.com
 Home Page (https://skcp.per.guni.ac.in/about/pharmaceutics-and-pharmaceutical-technology)

**DR. K. RAJYALAKSHMI** ()

Department of Pharmaceutical Chemistry, Vignan Pharmacy College, Vadlamudi, Guntur, A.P.
 Email: drkri3579@gmail.com
 Home Page (http://www.vignanpharmacycollege.in)

**SOURAVH BAIS** ()

474 VIP PARASPAR NAGAR
 Email: souravh2008.123@rediffmail.com
 Home Page (https://sageuniversity.in/pharmadetail#faculty)

**DR. D.S. JAYALAKSHMI** ()

Sathyabama Institute of Science and Technology (deemed to be University), Rajiv Gandhi Salai, OMR
 Email: jayananid10@gmail.com
 Home Page (https://www.sathyabama.ac.in/)

**DR. PARTHA NIYOGI** ()

SCHOOL OF PHARMACY THE NEOTIA UNIVERSITY SARISHA, DIAMOND HARBOUR WEST BENGAL- 743 368
 Email: parthaniyogi@tnuin
 Home Page (https://www.tnu.in/our_faculty/dr-partha-niyogi/)

**DR. RAJIV DUTTA** ()

Shobhit Institute of Engineering & Technology (Deemed-to-be-University) NH-58, Modipuram Meerut, UP-250110, India
 Email: director.sbt@gmail.com
 Home Page (rdutta.50megs.com)

<https://www.rjptonline.org/EditorialBoard.aspx>

18/46

**PRAVEEN KUMAR UPPALA** ()

LIG 163 Alakananda colony, Vizianagaram, Andhra Pradesh
 Email: praveen.chintu52@gmail.com
 Home Page (http://www.ipc.gov.in/)

**RAMAKRISHNA REDDY H** ()

#32, Shiva shakti, 4th Cross, KBL Elite layout, J.P.Nagar 8th Phase, Bangalore-560108, Karnataka state, India.
 Email: rkreddy_h@yahoo.co.in
 Home Page (https://www.apotex.com/in/contact-us)

**DR. PRAVIN KUMAR SHARMA** ()

Acropolis Institute of Pharmaceutical Education and Research, Indore
 Email: praveensharma910@gmail.com
 Home Page (https://aipcr.ac.in/)

**DR. FORAT YASIR ALJABERI** ()

Chemical Engineering Department, College of Engineering, Al-Muthanna University, Samawa, Iraq
 Email: furatyasir@mu.edu.iq
 Home Page (https://www.rjptonline.org/EditorialBoard.aspx)

**DR. L. NANDHAKUMAR** ()

Kastooribha gandhi Pharmacy college Namakkal, Rasipuram
 Email: drndkumar12@gmail.com
 Home Page (https://kgpc.edu.in/kgpc/index.php)

**PROF. DR. RAJIV DUTTA** ()

SHOBHIT UNIVERSITY, GANGOH
 Email: director.sbt@gmail.com
 Home Page (rdutta.50megs.com)

**AHMED ALI MHAWESH** ()

Baghdad/Iraq Al-Ghadeer Quarter
 Email: alohammarahmed.a.m@gmail.com
 Home Page (https://cv.nahrainuniv.edu.iq/ar/view/464)

**DR. JAGDISH KAKADIYA** ()

Department of Pharmacology, Parul Institute of Pharmacy and Research, Parul University, Vadodra, Gujarat, India
 Email: jagdishkakadiya@gmail.com
 Home Page (https://paruluniversity.ac.in/faculty/faculty-of-pharmacy/faculty-members)

<https://www.rjptonline.org/EditorialBoard.aspx>

19/46

**MAJIDA HAMEED KHAZAAL** ()

Kufa University
 Email: majdahamed69@yahoo.com
 Home Page (http://staff.uokufa.edu.iq/profile.html?majidah.alkhazaal)

**DR. SHOBHIT KUMAR** ()

Dr. Shobhit Kumar, Associate Professor, Department of Pharmaceutical Technology, Meerut Institute of Engineering and Technology (MIET), NH-58, Delhi-Roorkee Highway, Meerut-250005, Uttar Pradesh, India. Tel: +91 9675598375 E-mail: shobhitkmr87@gmail.com
 Email: shobhit.kumar@miet.ac.in
 Home Page (https://www.miet.ac.in/pharmacy)

**DR. P. DWARAKANADHA REDDY** ()

Annacharya College of Pharmacy, Rajampet-516126, Andhra Pradesh, India
 Email: dwarakanadhareddyperam@gmail.com
 Home Page (https://scholar.google.co.in/citations?user=OygvwmUAAAJ&hl=en)

**PROF. MATOLE VINOD KALIDAS** ()

Shivai Charitable trust's College of Pharmacy, Koregaonwadi Tal. Omerga Dist. Dharashiv Maharashtra India
 Email: matole7414@gmail.com
 Home Page (https://pru.ac.in/site/facultydetails?id=484)

**SANKARGANESH** ()

3/478, Ajith nagar, Sathankuppam, Kelambakkam-603103, Chennai, TN
 Email: bilisankar@gmail.com
 Home Page (https://hindustanuniv.ac.in/)

**ALAA HUSSEIN AL-DARRAJI** ()

Iraq-Misan
 Email: alaa.hussein@uomisan.edu.iq
 Home Page (https://www.researchgate.net/profile/Alaa-Al-Darraj/status/report/weekly/2022-06-12)

**MANISH KUMAR** ()

SD College, Barnala-148101, Punjab, India.
 Email: manish@sdcollegeinstitutions.org
 Home Page (http://sdcollegeinstitutions.org/SD.%20College/index.php)

DR. DINANATH TUKARAM GAIKWAD ()<https://www.rjptonline.org/EditorialBoard.aspx>

20/46



223, Shamrao Kumbhar Nagar, Nanapatil Nagar, Kolhapur, Maharashtra, India
 Email: gdinanath@gmail.com
 Home Page (<http://copkolhapur.bharatvidyapeeth.edu/>)



DR. AHMED HAMZA AL-SHAMMARI ()
 Iraq- Baghdad
 Email: Ahmed.h.mezaal@alkutcollege.edu.iq
 Home Page (<https://alkutcollege.edu.iq/ahmed-hamza/>)



KRISHNA PRASAD NARAPEREDDY ()
 1447 W Minerloop road, South Jordan, UT - 84095
 Email: krishna021@gmail.com
 Home Page (<https://www.reckitt.com/>)



MAJID MOHAMMED MAHMOOD ()
 majidm.mahmood93@uomustansiriyah.edu.iq
 Email: majidmahmood93@yahoo.com
 Home Page (<https://uomustansiriyah.edu.iq/e-learn/profile.php?id=687>)



DR. SATHISH KUMAR KONIDALA ()
 Associate Professor, Department of Pharmaceutical Sciences, Vignan's Foundation for Science Technology and Research (Deemed to be University), Vadlamudi, Guntur, A.P., India-522213.
 Email: ksh_pharma@vignan.ac.in
 Home Page (<https://vignan.ac.in/pharmafaculty.php>)



MOHAMED JABER ()
 University Road Aljurf P.O.Box 346
 Email: mohamed.jaber@ajman.ac.ae
 Home Page (www.ajman.ac.ae)



SANKARGANESH ()
 3/478, Sathankuppam, Kelambakkam-603103, TN
 Email: biisankar@gmail.com
 Home Page (<https://hindustanuniv.ac.in/assets/pdf/faculty/Food-Technology-faculty.pdf>)



DR. SWAMY NATHAN G ()
 Department of Biotechnology, College of Science and Humanities, SRM Institute of Science and Technology, India.
 Email: swamynathangesan.in@gmail.com
 Home Page (<https://www.srmist.edu.in/department/department-of-biotechnology-science-and-humanities/>)



DR. ANIL KUMAR TALLAM ()
 1350 Woodbourne Road, Apt-E74, Levittown, Pennsylvania, USA, Zip Code 19057
 Email: anilikumartallam1@gmail.com
 Home Page (<https://kvkitech.com/>)



BACHIR BEN SEGHIR ()
 Department of Process Engineering, Faculty of Technology, University of El Oued, BP 789, El-Oued 39000, Algeria
 Email: bbachir39@gmail.com
 Home Page (<https://profbachir.portfolial.com/#/>)



SUBRAMANIAN VETRISELVAN ()
 Assoc. Prof. Dr. Vetriselvan Subramanian, Ph.D. Deputy Dean M.Sc. and Ph.D. (by Research) Coordinator Faculty of Medicine, Bioscience and Nursing MAHSA University EC Member-Overseas, Indian Pharmacological Society (IPS)
 Email: vetricology@gmail.com
 Home Page (<https://mahsa.edu.my/>)



MAKSOOD ALI ()
 9 B, Near RK Public School, Aurangabad, District - Bulandshahr
 Email: drmal_pharmacy13@yahoo.com
 Home Page (<https://www.orleancollege.co.in/>)



DR. V. V. SATHIBABU UDDANDRAO ()
 Dr. V. V. Sathibabu Uddandhrao, Assistant Professor, Department of Biochemistry, K.S. Rangasamy College of Arts and Science (Autonomous), Tiruchengode-637215, Tamilnadu, India
 Email: sathibabu@gmail.com
 Home Page (<https://www.ksrcas.edu/>)



AYAN KUMAR KAR ()
 Rabindra Bhavan, D.C.Sankarara, Nimala, Tamluk -721636, East Medinipur, W.B., India
 Email: ayancipt@gmail.com
 Home Page (www.urschard.com)



DR. MOUMITA HAZRA ()
 Associate Professor, Department of Pharmacology, Shri Balaji Institute of Medical Science, Raipur, Chhattisgarh, India
 Email: drmoumitahazra.198017hjune@gmail.com
 Home Page (drmoumitahazra170680.blogspot.com)



SHIVAM TAVAI ()
 Jhansi Road, Gwalior
 Email: shivamtavalasp@tmuniversity.ac.in
 Home Page (<https://tmuniversity.ac.in/>)



FATMA BASSYOUNI ()
 National Research Centre, Cairo, Egypt
 Email: fatma.nrc.sc@gmail.com
 Home Page (<https://www.nrcs.ci.eg/>)



OJAS PRAKASHBHAI DOSHI ()
 Somerville, New Jersey, USA
 Email: doshiojas96@gmail.com
 Home Page (<https://cosettepharma.com/>)



DR. TANAJI NANDGUDE ()
 Sant Tukaram Nagar, Pimpri, Pune, Maharashtra - 411018
 Email: tanajinandgude@dypvp.edu.in
 Home Page (<https://pharmacy.dypvp.edu.in/>)



DR. RAJA CHAKRAVERTY ()
 5/1 Suri lane Kolkata 700014.
 Email: rchakraborty20@yahoo.com
 Home Page (<https://ipgmer.gov.in/>)



DR. TEJ BAHADUR CHANDRA ()
 School of Computer Science Engineering and Technology, Bennett University, TechZone 2, Greater Noida - 201310, Uttar Pradesh, India.
 Email: tejbahadur1990@gmail.com
 Home Page (<https://www.bennett.edu.in/faculties/tej-bahadur-chandra/>)



MAHMOUD BAHMANI ()
 Biotechnology and Medicinal Plants Research Center, Ilam University of Medical Sciences, Ilam, Iran
 Email: mahmood.bahmani@gmail.com
 Home Page (https://bpb.medilam.ac.ir/persons.php?ppup=1&slc_lang=en&sid=1&prsn_id=118)



DR. AMBER VYAS ()
 University Institute of Pharmacy, Pt. Ravishankar Shukla University, Raipur (C.G.) 492010
 Email: ambervyas@gmail.com
 Home Page (<https://prsu.ac.in/site/facultydetails?id=486>)



DR. A. PURUSHOTHAMAN ()
 PERI College of Arts and Science (Affiliated to University of Madras) PERI Knowledge Park, Mannivakkam Chennai-48, Tamil Nadu, India



Email: principalarts@peri.ac.in
 Home Page (<http://perieducation/pca/index.php>)



DR. ELIZABETH MARY MATHEW ()
 Plot 23211, Phase 4, Gaborone
 Email: mathewe@ub.ac.bw
 Home Page (<https://www.ub.bw/connect/staff/11569>)



DR. RAKHI MISHRA ()
 Noida Institute of Engineering and Technology Pharmacy Institute, Knowledge Park 2, Plot 19, Greater Noida 201306
 Email: rakhimishra.pharmacy@niet.co.in
 Home Page (<https://nietpharmacy.co.in/>)



DR. J ADLIN JINO NESALINI ()
 T John College of Pharmacy, Gottigere, Bangalore.
 Email: adlinjino@gmail.com
 Home Page (<https://www.tjohncollege.com/>)



BEHZAD FOROUTAN ()
 Department of Pharmacology School of Medicine Shahrood University of Medical Sciences Shahrood, IRAN
 Email: behzad_foroutan@hotmail.com
 Home Page ()



DR. AMIT ROY ()
 Principal, Columbia Institute of Pharmacy, Raipur CG India
 Email: wakratund@gmail.com
 Home Page ()



P. PARTHIBAN ()
 Centre for R&D, PRIST University, Thanjavur-613403, India
 Email: parthisivam@yahoo.co.in
 Home Page ()



PROF. D. K. TRIPATHI ()
 Principal, Rungta Institute of Pharmaceutical Sci. and Research, Bilai CG India
 Email: editorrjpt@gmail.com
 Home Page ()



Assistant Professor, Department of Biotechnology, Vysya College, Masinaickenpatty, Salem- 636103. Tamil Nadu, India.
Email: kumaravelbiotech@gmail.com
🏠 Home Page ()



DR GIRISH PAI K ()
Faculty - Dept of Pharmaceutics Manipal college of pharmaceutical sciences Manipal University, Madhav Nagar Manipal - 576104, Karnataka State, India
Email: girish.pai@manipal.edu
🏠 Home Page ()



DR. AJAY V. PATHAK ()
House No.33 Ravindra nagar Nagpur-440022 Maharashtra, INDIA
Email: a.pathak4@gmail.com
🏠 Home Page ()



AYUSH DOGRA ()
department of electronics and communications, panjab university chandigarh
Email: ayush123456789@gmail.com
🏠 Home Page ()



DR. PRATIBHA VYAS ()
Department of Microbiology, College of Basic Sciences and Humanities, Punjab Agricultural University, Ludhiana-141004, Punjab, India.
Email: pratibha.19064@pu.co.in
🏠 Home Page ()



IHSAN HABIB DAKHIL ()
Engineering College, Al-Muthanna University, Iraq
Email: ihsanhabib@yahoo.com
🏠 Home Page ()



DR.JAYASHREE SEN ()
J.N.M.C.&A.V.B.R.H.,Sawangi,Wardha,Maharashtra 442007
Email: jayashree_sen@rediffmail.com
🏠 Home Page ()



IMAD ()
University of Babylon
Email: imad_dna@yahoo.com
🏠 Home Page ()



RIM M. HARFOUCH ()
Al Andalus university, Qadmus, Tartous, Syria
Email: rimharfouch@au.edu.sy
🏠 Home Page ()



MOHAMMAD JAWAD AL-JASSANI ()
Department of Microbiology, College of Science, Al-Karkh University of Science, Iraq.
Email: pcr2000@yahoo.com
🏠 Home Page ()

REVIEWERS



DR. SUBHASHIS DEBNATH ()
Seven Hills College of Pharmacy Venkatramapuram, Tirupati- 517561
Email: subshasis.ooty@gmail.com
🏠 Home Page ()



GAURAV KUMAR ()
Department of Microbiology School of Bioengineering and Biosciences Lovely Professional University Phagwara, 144411, Punjab, India
Email: gau_ravkr@yahoo.com
🏠 Home Page ()



RUCHI VERMA ()
manipal college of pharmaceutical sciences, manipal university, karnataka, India.
Email: ruchi.verma@manipal.edu
🏠 Home Page ()



DR. KETAN VINODLAL SHAH ()
201, Rudrax Apartment, Guruprasad Society, Nehind Telephone exchange, Krishnanagar Main road, Rajkot
Email: ketan421981@gmail.com
🏠 Home Page ()



K SUJANA ()
university college of pharmaceutical sciences Acharya Nagarjuna university
Email: sujana_36@yahoo.co.in
🏠 Home Page ()

DR.PBRINDHA DEVI ()



Vels University, Velan Nagar, PV Vaithiyalingam Road, Pallavaram
Email: pbrindhadevi@gmail.com
🏠 Home Page ()



DR VAMSHI KRISHNA TIPPVAJHALA ()
Assistant Professor-Senior Scale Department of Pharmaceutics Manipal College of Pharmaceutical Sciences Manipal University Manipal, Karnataka, India
Email: krissrcm@gmail.com
🏠 Home Page ()



ZAIN BAATY ()
Syria, Latakia
Email: zein_syria@hotmail.com
🏠 Home Page ()



LAITH AHMED NAJAM ()
Mosul University, College of Science, Physics Dept., Mosul
Email: ProfLai2014@gmail.com
🏠 Home Page ()



VEEREN DEWOOLKAR ()
4824 Washtenaw Ave, Apt C1, Ann Arbor, MI 48108
Email: veerenrx@gmail.com
🏠 Home Page ()



NEERAN OBIED JASIM ()
University of Al-Qadisiyah college of Pharmacy Iraq
Email: neran.jasim@qu.edu.iq
🏠 Home Page ()



MAHMOUD NAJIM ABID ()
Mustansiriyah University, College of Science, Department of Chemistry
Email: mahmoudalibouri@gmail.com
🏠 Home Page ()



NILESH PATEL ()
B/103,Snehkunj Elegance,Behind Shivalay Parisar Kudasan,Gandhinagar-382421,Gujarat
Email: nilesh33emcure@gmail.com
🏠 Home Page ()



NEERAN OBIED JASIM ()
university of Al-Qadisiyah -college of science-Iraq
Email: neran.jasim@qu.edu.iq
🏠 Home Page ()



MARWAN MAHMOOD SALEH ()
Anbar-Ramadi- Habbaniya- 4-4-17
Email: ahmarwan_bio@uoanbar.edu.iq
🏠 Home Page ()



PALLAVI LAXMAN PHALKE ()
Parul University, Limda, Waghodiya, Vadodara-391760, Gujarat India.
Email: falkepallavi@gmail.com
🏠 Home Page ()



DR. ANUP S. HENDRE ()
Biochemistry Department Krishna Institute of Medical Sciences, Malkapur Karad, Dist-Satara.
Email: anavivies@gmail.com
🏠 Home Page ()



SURENDRA KUMAR GAUTAM ()
Kamla Nehru Institute of Management & Technology, NH96 Faizabad Bypass Road Faridpur Campus
Email: surendra_bkt95@yahoo.in
🏠 Home Page ()



DR U R RAKSHITH ()
Dr U R Rakshith Lecturer JSS College of Pharmacy, JSS Academy of Higher Education and Research Shivarathreeswara Nagar, Mysuru- 570015 Karnataka, India
Email: urrakshith@jssuni.edu.in
🏠 Home Page ()



RAMU SAMINENI ()
H.NO-1,123 A, C/O SIVARAMAKRISHNA SAMINENI MANDEPUDI, AMARAVATHI
Email: samineni.ramu@gmail.com
🏠 Home Page ()



DHAVAL PATEL ()
A-104, Maruti Aamrakunj, Sargasan, Gandhinagar-382421
Email: dhavaln9ine@gmail.com
🏠 Home Page ()

**AKHIL NAGAR ()**

R C PATEL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
Email: akkisharma23@gmail.com
Home Page ()

**SUNANDAR IHSAN ()**

Kampus Hijau Bumi Tridharma Universitas Halu Oleo Fakultas Farmasi, Jl.H.E.A.Mokodompit Andouhuh, Kendari, Indonesia
Email: sunandarhsan@uho.ac.id
Home Page ()

**ANAS TARIK NAFEI ()**

Baghdad, Qadissiyah Express way
Email: anasalhamdany@yahoo.com
Home Page ()

**DR.KUMARASWAMY GULLAPELLE ()**

STREET NUMBER 4, BHAVANI NAGAR, NACHARAM, HYDERABAD NACHARAM, Hyderabad, Telangana, pincode: 500076
Email: kumargullapelli001@gmail.com
Home Page ()

**RADHWAN AL-ZIDAN ()**

Almothana district, Mosul, Iraq
Email: radhwan.alzidan@uosmosul.edu.iq
Home Page ()

**YAHIA M. MOUALLA ()**

faculty of pharmacy, Tishreen university, Latakia, Syria
Email: yahia.moualla@tishreen.edu.sy
Home Page ()

**SUHASS SURESH AWATI ()**

Assistant Professor, Dr. Shivajirao Kadam College of Pharmacy, Kasabe Digrav, Baganvat, Tal- Miraj, Dist- Sangli, Maharashtra. 416301
Email: awatiss@gmail.com
Home Page ()

SHAIK FIROZ ()

Assistant Professor, Department of Pharmaceutics, Sree Vidyanikethan College of Pharmacy, Sree Sainath Nagar, A.Rangampet-517102.



Email: firoz.kallur@gmail.com
Home Page ()

**DR NASEEF PP ()**

Vice Principal, Mouana College of Pharmacy, Near Angadippuram Railway Station, Malappuram, Kerala, India 679321
Email: drnaseefpp@gmail.com
Home Page ()

**DR. ARINDAM CHATTERJEE ()**

School of Pharmaceutical Sciences Jaipur National University (SADTM Campus) Near RTO Office, Jaipur Agra
Bypass Jagatpura, Jaipur, Rajasthan India-302017
Email: chatterjee.arindam@hotmail.com
Home Page ()

**S RAJARAJAN ()**

Department of Pharmaceutics, Karnataka College of Pharmacy 33/2, Thirumena Halli, Hegde Nagar Main Road, Bangalore-560064
Email: pharmking@gmail.com
Home Page ()

**DR . RAHUL RADHAKRISHNAN ()**

Manasam, Edavattom, Chirakkara (PO), Kollam, Kerala
Email: drrahulpharmd@gmail.com
Home Page ()

**RIM M. HARFOUCH ()**

0624 Albaath street, Latakia, Syria
Email: rimharfi@yahoo.com
Home Page ()

**ARUN A ()**

3/31 periyar street, ramapuram chennai 600089
Email: arunarticle2016@gmail.com
Home Page ()

**ABDUL SALEEM MOHAMMAD ()**

Department of Pharmaceutical Analysis and Quality Assurance, Nizam Institute of Pharmacy, Deshmukhi (V), Pochampally (M), Behind Mount Opera, Nalgonda (Dist)-508284, Telangana, India.
Email: mohdsaleempharma@gmail.com
Home Page ()

**KARTHIKEYAN T ()**

registrar nishans
Email: karthik_77in@yahoo.co.in
Home Page ()

**DR. PUTTA RAJESH KUMAR ()**

Amdapur X Road, Yenkapally, Moinabad, Ranga Reddy, Hyderabad, Telangana 500075 INDIA
Email: prkbpcc@gmail.com
Home Page ()

**AAMINAH NAJMUS SAHAR ()**

H.No: 121, Pension lane, New Bowenpally Secunderabad- 500011
Email: aaminahnajmus@yahoo.in
Home Page ()

**ZAINAB HAITHAM FATHI ()**

College of Pharmacy, University of Mosul
Email: zainabfathi@uomosul.edu.iq
Home Page ()

**DR. OM PRAKASH RANJAN ()**

Faculty of Pharmacy, Sachchidanad Sinha College, Aurangabad, Bihar.
Email: omprakasranjan@gmail.com
Home Page ()

**SHASHIKANT SUDARSHAN UPADHYE ()**

Annasaheb Dange College of B.Pharmacy, Ashta Tal: Walwa, Dist: Sangli 416301, Maharashtra, India
Email: ssupadhye7@gmail.com
Home Page ()

**VISHAL KUMAR BISWARKARMA ()**

KSCP, Subharti University, Meerut, Uttar Pradesh, India
Email: vishalkumarbiswarkarma@gmail.com
Home Page ()

**DR. C. JANANI ()**

Dr. C. Janani, Srividya Arts and Science College, Nelson Road, TV Kovil, Trichy-05
Email: janabio.net@gmail.com
Home Page ()

**RANJAN KUMAR SINGH ()**

g d memorial college of pharmacy, kbhb, jodhpur, 342005
Email: rnsingh8@gmail.com
Home Page ()

**BIMESH KUMAR ()**

BLOCK 4, ROOM NO 203, SCHOOL OF PHARMACEUTICAL SCIENCES, LOVELY PROFESSIONAL UNIVERSITY, PHAGWARA, PUNJAB, 144411.
Email: bimlesh1pham@gmail.com
Home Page ()

**DR BISWARANJAN RAY ()**

Associate prof, Dept. of Pharmacology, College of Pharmaceutical Sciences, Puri Odisha
Email: crabisws@gmail.com
Home Page ()

**ANAR J PATEL ()**

Sal Institute of Pharmacy, Ahmedabad
Email: anar.patel@sal.edu.in
Home Page ()

**GANESH BARKADE ()**

Dr. Vithalrao Vikhe Patil Foundation's College of Pharmacy, Ahmednagar, MH, India-414111 Vikhe Patil Foundation
Email: ganeshbarkade7@gmail.com
Home Page ()

**DR. VEDAMURTHY JOSHI ()**

Associate professor, Sri Adichunchanagiri College of Pharmacy, BG Nagara Nagamangala Tq Mandya dist Karnata
Email: vedamurthyjoshi@gmail.com
Home Page ()

**AVINASH BABURAO THALKARI ()**

Kanadi Road Kajj Vasant Pharmacy College Kajj Kanadi Road Kajj
Email: avinashthalkari@gmail.com
Home Page ()

DR. P. PRAVEEN REDDY ()

Vivekananda Degree and PG College, Karimnagar-505001, Telangana



Email: microprr@gmail.com
 Home Page ()



MUTHUKUMARKUMAR.S ()
 45,U.K.Thevar Street, Sulur, Coimbatore-641402
 Email: pharmmuthu@gmail.com
 Home Page ()



D CHANDRA SEKHAH NAIK ()
 KVSR Siddhartha college of pharmaceutical sciences poly clinical road Vijayawada-10
 Email: chandudesaavath@gmail.com
 Home Page ()



BHARAT MISHRA ()
 Nirmala college of pharmacy, Nirmala Hills, Muvattupuzha, Emakulam, Kerala, India
 Email: bharatekansh@gmail.com
 Home Page ()



MATOLE VINOD KALIDAS ()
 AT POST AJRAD TAL.OMERGA DIST. OSMANABAD
 Email: vinodmatole57@gmail.com
 Home Page ()



NIRMAL THAKKER ()
 B-602, Tirupati Askruvi Greenz, Behind Nirma University, S.G. Highway, Ahmedabad-382481, Gujarat, India
 Email: nirmalthakker117@yahoo.com
 Home Page ()



JASWANTH GOWDA B.H. ()
 Yenepoya (Deemed to be University), Deralakatte, Mangalore, India-575018.
 Email: jaswanth_14601@yenepoya.edu.in
 Home Page ()



ZEINA ABDULMUNIM ALTHANNOON ()
 Albaladyat Quarter Mosul Iraq
 Email: ph.zeinalthannoon@gmail.com
 Home Page ()

SHIVAVEERAKUMAR ()

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Department of Microbiology, Davangere University, Davanagere - 577002, Karnataka
 Email: shiv_math1984@rediffmail.com
 Home Page ()



DR.V.K.EVANJELENE ()
 16, Anbu Nagar, gorimedu, Salem - 636 008
 Email: evankutty@gmail.com
 Home Page ()



ASHISH TALE ()
 MJPS College of Pharmacy, Degaon, Tq. Risod, Dist. Washim-444506 (M.S) India
 Email: ashishtale93@gmail.com
 Home Page ()



DR. C. JANANI ()
 Srimad Andavan Arts and Science College, Nelson Road, TV Kovil TV kovil
 Email: janabionet@gmail.com
 Home Page ()



PRATHEEP THANGARAJ ()
 Department of Biotechnology, PRIST Deemed to be University, Thanjavur-613403, India.
 Email: pratheept@gmail.com
 Home Page ()



SHAIMAA AHMAD HASSAN ()
 AlKarkh University of science / Baghdad / Iraq
 Email: drshaimaa_altaee@kus.edu.iq
 Home Page ()



DR ANUP NAHA ()
 Manipal College of Pharmaceutical Sciences, MAHE, Manipal, Karnataka-576104
 Email: anupnaha@gmail.com
 Home Page ()



EIMAN SHAHROUR ()
 lattaikia- syria
 Email: eimanm.shahrou@gmail.com
 Home Page ()

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DR. DEVAKUMAR DINESH ()
 Department of Zoology, Bharathiar University Coimbatore-641046 Tamilnadu India
 Email: devdinesh4041@gmail.com
 Home Page ()



AUDUMBAR DIGAMBAR MALI ()
 At. Po. Andhalgaon, Tal-mangalwedha, Dist- Solapur, Pin Code:- 413305, Maharashtra, India.
 Email: maliaudu442@gmail.com
 Home Page ()



DR. MITTAL MAHESHWARI ()
 A- One Pharmacy College, Ahmedabad
 Email: mittalmaheshwary@gmail.com
 Home Page ()



ABDUL AZEEM ()
 Research Scholar, Electrical Engineering Department Jamia Millia Islamia-New Delhi
 Email: azeemth@gmail.com
 Home Page ()



DR. V. VADIVEL ()
 PG & Research Department of Botany, V.O. Chidambaram College, Tuticorin - 628008 Tamil Nadu, India
 Email: drvadvivel@gmail.com
 Home Page ()



PROF.(DR.) KUMARASWAMY GANDLA ()
 Dr.Kumara SwamyGandla Associate Editor of RJPT (Research journal of Pharmacy and Technology Chaitanya Deemed to be University, Hanamkonda, Warangal-Urban (Dist), Telangana 506001-India. Mobile: +91-9000973789 / +91-7801022789
 Email: drkumaraswamygandla@gmail.com
 Home Page ()



MR. PATIL AMOL MANIK ()
 AT/P- KASEGAON TAL- WALWA DIST- SANGLI PIN CODE- 415404 MAHARASHTRA
 Email: amp6389@gmail.com
 Home Page ()



MOH MIRZA NURYADY ()
 Blok HC No. 14, Jl. Intan 2, Perum GPA, Ngijo, Kec. Karangploso, Kabupaten Malang, East Java
 Email: mirzanuryady@umm.ac.id
 Home Page ()

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SHAIMAA AHMAD HASSAN ()
 College of Remote Sensing & Geophysics, Al Karkh University of Science, Baghdad, Iraq
 Email: drshaimaa_altaee@kus.edu.iq
 Home Page ()



MAUSAMI VAGHELA ()
 New College Wadi-3, B/H Punjab Honda, Opp. sitvan Flat, Kalawad Road, Rajkot.
 Email: mausami_2123@yahoo.com
 Home Page ()



KOTESHWARA MUDIGONDA ()
 Siven Life Sciences Limited, Hyderabad, India
 Email: koteshwara_mudigonda@yahoo.com
 Home Page ()



DR. SWAMY C T ()
 51, Anna Arch Rd, NSK Nagar, Anna Nagar, AA Hospital Campus
 Email: swamyc23@gmail.com
 Home Page ()



KHUDHAIR ABBAS KAREEM AL-RUDAI ()
 Iraq, Baghdad
 Email: khudhair.2010@yahoo.com
 Home Page ()



BALJEET YADAV ()
 1202 H, Coralwood Sector 84, Gurugram INDIA
 Email: baljeetyadav@gdgu.org
 Home Page ()




DR NILIMA ABHIJEET THOMBRE ()
 MET's Institute Of Pharmacy, Bhujbal Knowledge City, Adgaon, Nasik-422003, Maharashtra, India. nilimat_jop@bkc.met.edu 09422284082
 09960646693
 Email: nilimat_jop@bkc.met.edu
 Home Page ()

SNIGDHO DAS ()


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Email: sivakumar.j@gurunanakcollege.edu.in
 Home Page (https://gurunanakcollege.edu.in/school-of-science)




DR.V.N.INDULATHA ()
 8/SORC Nagar extension, Othakkalmandapam, Coimbatore, Tamilnadu, India
 Email: profindulatha@gmail.com
 Home Page (https://nchs.nirmalcollege.edu.in)




RISHIKESH BACHHAV ()
 Anjaneri, Trymbakeshwar
 Email: bachhavrs@rediffmail.com
 Home Page (https://www.sspkalpharmacy.org)




DR. M.S. ARUN ()
 Faculty of Pharmacy, JKKN College of Pharmacy, Kumarapalayam, Namakkal - 638183.
 Email: arun.ms@jkn.ac.in
 Home Page (www.pharmacyjkn.ac.in)




DEEPANJAN DATTA ()
 Department of Pharmacy Lloyd Institute of Management & Technology (Pharm.) Plot No.11, Knowledge Park 2 Greater Noida, U.P. 201306
 Email: deepanjan.datta@lloydpharmacy.edu.in
 Home Page (https://lloydpharmacy.edu.in/)



DR. L. NANDHAKUMAR, M. PHARM, P ()
 521, Perur Main Rd, Telungu Palayam Pirivu, Priya Nagar, Selvapuram South, Coimbatore, Tamil Nadu 641008
 Email: drnkumar12@gmail.com
 Home Page (https://www.ccp.ac.in/)




ATUL SHIVAJI GURAV ()
 Vidyanagar, Karad, Satara, MS, India
 Email: atulgurav800@gmail.com
 Home Page (http://dcpmasur.com/)




DR. SABER ABBASZADEH ()
 Department of Biochemistry and genetics, Lorestan University of Medical Sciences, Khorramabad, Iran
 Email: drsaberabbaszadeh20@gmail.com
 Home Page (https://www.scopus.com/authid/detail.uri?authorId=57194335679)

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Plot No. 23, Jote Joy Building, Rambhau Salgaonkar Road, Cuffe Parade, Mumbai 400 005, Maharashtra, India
 Email: np.rajnani@kmkcp.edu.in
 Home Page (https://kmkcp.edu.in/)



NIKHIL RAJNANI ()
 Plot No. 23, Jote Joy Building, Rambhau Salgaonkar Rd, Cuffe Parade, Mumbai, Maharashtra 400005
 Email: np.rajnani@kmkcp.edu.in
 Home Page (https://kmkcp.edu.in/staff/)



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RESEARCH ARTICLE

Evaluation of Efficacy and Side Effects of Impairment Liver Function in Psoriasis Vulgaris Patients Treated with Methotrexate in Dr. Soetomo General Academic Hospital Surabaya: A Retrospective Study

Ira Yunita¹, Afif Nurul Hidayati¹, Muhammad Yulianto Listiawan¹, Evy Ervianti¹, Budi Utomo², Damayanti¹, Sylvia Anggraeni¹, Menul Ayu Umborowati¹, Cita Rosita Sigit Prakoeswa^{1*}

¹Department of Dermatology and Venereology, Universitas Airlangga/ Dr. Soetomo General Academic Teaching Hospital, Universitas Airlangga Teaching Hospital, Surabaya, Indonesia.

²Department of Public Health Sciences, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia.

*Corresponding Author E-mail: cita-rosita@fk.unair.ac.id

ABSTRACT:

Background: Psoriasis is a chronic inflammatory skin disease that involves several factors, genetic, immunity defects, hormones, and environmental factors. Psoriasis vulgaris is often characterized by a thick, erythematous, well-defined, rough, layered, silvery white plaque. Methotrexate is a first-line systemic therapy in the management of psoriasis vulgaris. This drug effective to reduce the severity of the disease by at least 50% in more than 75% of patients. Unfortunately, methotrexate also has the potential to cause adverse effects, this drug is considered one of the main causes of increased liver enzymes in psoriasis patients for several years so special consideration is needed when prescribing methotrexate to patients. Therefore, periodic evaluation during the use of this drug is needed to find out the side effects that can be caused. **Purpose:** The aim was to to evaluate PASI, SGOT and SGPT score of psoriasis vulgaris patients who received methotrexate therapy at Dermatology and Venerology Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya. **Methods:** This was a observational analytical study with retrospective data through one shot case study pre-experimental study approach, but was conducted pre and post treatment that aimed to evaluate PASI, SGOT and SGPT score of psoriasis vulgaris patients who received methotrexate therapy at Dermatology and Venerology Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya for the period January 2018-December 2020. **Results:** The results of this study were 51 psoriasis patients who received methotrexate that include in inclusion criteria. The number of male patients was more than women, 30(58,8%) for men and 21(41.2%) for women. There was a statistically significant difference in the reduction in PASI score of psoriasis vulgaris patients before and after methotrexate therapy ($p = 0.001$). However, the results of statistical analysis SGOT score of psoriasis vulgaris patients before methotrexate therapy were no different than after receiving methotrexate therapy ($p = 0.286$). In contrast, the results of statistical analysis SGPT score of psoriasis vulgaris patients after receiving methotrexate therapy increased significantly compared to before receiving methotrexate therapy ($p = 0.001$). **Conclusion:** there was significant decrease in PASI scores and significant increase in SGPT scores before and after receiving methorexate therapy. However, for SGOT scores statistically there was no significant difference before and after receiving methorexate therapy.

KEYWORDS: Psoriasis vulgaris, Methotrexate, PASI, SGOT, SGPT.

INTRODUCTION:

Psoriasis is a chronic inflammatory skin disease that involves several factors, genetic, immunity defects, hormones, and environmental factors. Psoriasis vulgaris is often characterized by a thick, erythematous, well-defined, rough, layered, silvery white plaque.¹ Psoriasis vulgaris, also called plaque type psoriasis, is the most common type, occurring in about 90% of

patients. The prevalence of psoriasis patients in Indonesia varies. Data in Dermatology and Venerology Outpatient Clinic Dr. Soetomo General Academic Hospital Surabaya showed that in 2013, there were 0.46% new cases of psoriasis vulgaris from a total of 5,454 new visiting patients.² Appropriate, safe, and effective therapy is indispensable for psoriasis vulgaris patients. Psoriasis therapy options include topical therapy, phototherapy, systemic, and biological agents. Systemic therapy are prescribed for severe and widespread psoriasis.³ This drug effective to reduce the severity of the disease by at least 50% in more than 75% of patients. Methotrexate is an antifolate that competitively binds to dihydrofolate reductase (DHFR) which inhibits precursors of DNA and RNA and inhibits cell replication. It is an important drug in treatment of an acute lymphoblastic leukemia (ALL), choriocarcinoma, related trophoblastic tumors and psoriasis.⁴ Methotrexate competitively and reversibly inhibits dihydrofolate reductase (DHFR), an enzyme that participates in the tetrahydrofolate synthesis.⁵ Methotrexate goes about as anti-proliferative and a mitigating specialist against the cells causing psoriasis vulgaris inflammation.⁶ Unfortunately, methotrexate also has the potential to cause adverse effects, this drug is considered one of the main causes of increased liver enzymes in psoriasis patients for several years so special consideration is needed when prescribing methotrexate to patients.⁷ The liver has an enormous task of maintaining the body's metabolic homeostasis. This includes, the processing of dietary amino acids, carbohydrates, lipids, and vitamins; synthesis of serum proteins; and detoxification and excretion into bile of endogenous waste products and pollutant xenobiotics.⁸ The liver is the principle organ of metabolism and excretion is subject to a number of diseases which may be classed as liver cirrhosis (cell destruction and increase in fibrous tissue), acute chronic hepatitis (non inflammatory condition) jaundice a yellow fever discoloration of the skin and eyes caused by bile in the blob is the symptom of blockage of the bile duct or disease within the tissue of the liver itself.⁹ Therefore, periodic evaluation during the use of this drug is needed to find out the side effects that can be caused.

METHODS:

This study was observational analytical study with retrospective data through one shot case study pre-experimental study approach, but was conducted pre and post treatment that aimed to evaluate PASI, SGOT and SGPT score of psoriasis vulgaris patients who received methotrexate therapy at Dermatology and Venerology Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya for the period January 2018 - December 2020, using secondary data in the form of medical record data. This study has received ethical

approval from the Hospital Ethics Committee RSUD Dr. Soetomo Surabaya (0684/LOE/301.4.2/XI/2021). The inclusion criteria were all patients recorded in the medical record with a diagnosis of psoriasis vulgaris, while the exclusion criteria were patients without psoriasis vulgaris, patients who stop undergoing methotrexate therapy and there was no follow-up 2 consecutive cycles, and patients who undergo laboratory examination of liver function tests other than in the clinical pathology laboratory of Dr. Soetomo Hospital.

RESULT:

This study obtained of 315 patients of psoriasis vulgaris, both new and old patients who were treated at Dermatology and Venerology Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya for the period January 2018 - December 2020. Psoriasis vulgaris patients who received methotrexate therapy were 132 patients. There were a total of 51 psoriasis vulgaris patients who met the study inclusion criteria.

Table 1: Distribution of psoriasis vulgaris patients receiving methotrexate therapy

Variable	Total (n=51)
Gender, n (%)	
Male	30 (58.8)
Female	21 (41.2)
Age range, n (%)	40.96 (15-72)
Age category (Kemenkes RI, 2009)	
0-5 years old	0 (0)
5-11 years old	0 (0)
12-16 years old	2 (3.92)
17-25 years old	11 (21.56)
26-35 years old	8 (15.69)
36-45 years old	5 (9.80)
46-55 years old	16 (31.38)
56-65 years old	8 (15.69)
>65 years old	1 (1.96)
PASI scores, n (%)	
Mild (<5)	0 (0)
Moderate (5-10)	2 (3.9)
Severe (>10)	49 (96.1)

The results showed that the number of male patients was higher than female which are 30 (58.8%) in male and 21 (41.2%) in female. The average age was 40.96 years with the youngest age being 15 years and the oldest age being 72 years old. Distribution of severity degrees based on initial PASI scores before receiving methotrexate therapy were 2 patients (3.9%) experienced moderate severity and 49 patients (96.1%) experienced severe severity.

Table 2: Evaluation of PASI scores initials, follow-up 1, and follow-up 2 of psoriasis vulgaris patients before and after receiving methotrexate therapy.

	n	Mean ± SD	p value all
SGOT Initials	51	23.39 ± 8.98	0.286*
SGOT Follow-up 1	51	25.33 ± 9.72	
SGOT Follow-up 2	51	23.49 ± 70.1	

*Friedman Test , **Wilcoxon test declared significant p value < 0.05

Statistical analysis were showed p value = 0.001 which showed that there was a statistically meaningful difference in the decrease in PASI scores before and after receiving methotrexate therapy in follow-up 1 and

2. Then a post hoc test was conducted that showed that a significant decrease in PASI scores was obtained at initials vs follow-up 1 vs follow-up 2.

Table 3. Evaluation of SGOT values initials, follow-up 1, and follow-up 2 of psoriasis vulgaris patients before and after receiving methotrexate therapy.

	n	Mean ± SD	p value all	p value PASI Initials vs PASI Follow-up 1	p value PASI Initials vs PASI Follow-up 2	p value PASI Follow-up 1 vs PASI Follow-up 2
PASI Initials	51	20.32 ± 7.49	0.001*	0.001**	0.001**	0.001**
PASI Follow-up 1	51	12.56 ± 5.82				
PASI Follow-up 2	51	7.96 ± 5.24				

*Anova Test same subject , **Pairwise Comparasion declared siqnificant p value < 0.05

Statistical analysis were showed p value = 0.286 which showed that there was no statistically meaningful difference in the increase in SGOT values before and after receiving methotrexate therapy in follow-up 1 and

2. Then a post hoc test was conducted that showed that there was no significant increase in SGOT value at the initials vs follow-up 1 vs follow-up 2.

Table 4. Evaluation of SGPT values initials, follow-up 1, and follow-up 2 of psoriasis vulgaris patients before and after receiving methotrexate therapy.

	n	Mean ± SD	p value all	p value SGPT Initials vs SGPT Follow-up 1	p value SGPT Initials vs SGPT Follow-up 2	p value SGPT Follow-up 1 vs SGPT Follow-up 2
SGPT Initials	51	30.33 ± 13.95	0.001*	0.003**	0.219**	1.000**
SGPT Follow-up 1	51	35.65 ± 20.31				
SGPT Follow-up 2	51	30.33 ± 13.95				

*Anova Test same subject , **Pairwise Comparasion declared siqnificant p value < 0.05

Statistical analysis were showed p value = 0.001 which showed that there was a statistically meaningful difference to the increase in SGPT values before and after receiving methotrexate therapy in follow-up 1 and 2. Then a post hoc test was conducted that showed that a significant increase in the value of SGPT at the initials vs follow-up 1 while at the SGPT value initials vs follow-up 2 and SGPT follow-up 1 vs follow-up 2 did not get a significant increase.

women 6 patients (37.5%).² Men and women have an equally large prevalence, but recent studies have shown that psoriasis is slightly more common in men than women.¹⁰ The prevalence of psoriasis in men and women has an equally large prevalence, but it is found to be slightly more common in men. This can be because the clinical manifestations of psoriasis in men are often more severe so that male patients are more often to come for treatment to the hospital. Men also tend to have a higher risk of obesity and metabolic disease than women, and the influence of smoking and consuming alcohol which is likely to be higher in male patients can be a triggering factor for psoriasis.¹¹

DISCUSSION:

The results of this study showed that total 315 psoriasis vulgaris patients, both new and old patients who were treated in the Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya for the period January 2018 - December 2020. The number of psoriasis vulgaris patients who received methotrexate therapy were 51 patients who met the criteria for research inclusion. The gender distribution of psoriasis vulgaris who were treated in the Outpatient and Inpatient Clinic Dr. Soetomo General Academic Hospital Surabaya for the period January 2018-December 2020 showed that female patients was higher than men, 164(52.1%) in women and 151(47.9%) in men. But, the gender distribution of psoriasis vulgaris patients who received methotrexate therapy showed that male patients was higher than women, namely 30 (58.8%) in men and 21(41.2%) in women.

Distribution severity of psoriasis vulgaris patients before receiving methotrexate therapy were 2 patients (3.9%) experienced moderate severity and 49 patients (96.1%) experienced severe severity. This retrospective study showed that there were 29 patients who experienced a decrease in PASI scores after receiving methotrexate therapy. Statistical analysis were showed p value = 0.001 which showed that there was a statistically significant difference in the decrease in PASI scores before and after receiving methotrexate therapy. This is in accordance with research by Cabello and colleagues on 218 psoriasis vulgaris patients with moderate to severe severity, methotrexate was shown to help lower PASI scores significantly.¹² Methotrexate has been approved as a recommended first-line systemic therapy in moderate to severe degrees of psoriasis vulgaris.¹³ In light of the therapeutic condition and response to treatment, its dosage and frequency of use can be

Data from Outpatient Clinic Dr. Soetomo General Academic Hospital Surabaya in 2013 showed the distribution of gender was male 10 patients (62.5%) and

determined.¹⁴ Methotrexate has a cell cycle specific action-kills cells in S phase; primarily inhibits DNA Synthesis, but also affects RNA and protein synthesis. It is an anti-metabolite and antifolate drug used in treatment of psoriasis.¹⁵

This retrospective study research showed that there were 2 patients who experienced an increase in SGOT scores after receiving methotrexate therapy. The most common side effects of methotrexate are gastrointestinal manifestations such as nausea, vomiting, stomatitis, loss of appetite and hepatotoxicity effects.¹⁶ But, in this study statistical analysis were showed p value = 0.286 which showed that there was no statistically meaningful difference in the increase in SGOT scores before and after receiving methotrexate therapy. This is in accordance with a study that reporting 68.2% of psoriasis vulgaris patients observed had normal SGOT levels after receiving methotrexate therapy, and only 18.2% of patients experienced elevated levels of SGOT. From 45.5% of patients experienced an increase in SGOT but still within normal limits.¹ Liver is the largest glandular and major organ for metabolism. The liver reacts with different types of responses to injury in response to variety of metabolic, toxic, microbial, circulation and neoplastic insults. Hepatic injury leads to disturbances in transport function of hepatocytes resulting in leakage of plasma membrane thereby causing an increased enzyme level in serum.¹⁷ Enzymes SGOT and SGPT are associated with the parenchyma of liver cells, the difference is that SGPT is found more in the liver whereas SGOT is found in the liver, heart muscle, skeletal muscle, kidneys, brain, and red blood cells. Therefore, SGPT is a more specific indicator of liver inflammation than SGOT. Enzymes SGOT can increase in diseases that can affect other organs, such as myocardial infarction, acute pancreatitis, acute hemolytic anemia, severe burns, acute kidney disease, musculoskeletal disease, and trauma.¹⁸ This is in accordance with this retrospective study because it does not mean statistically the value of SGOT which shows that SGOT may not be a specific indicator in assessing liver inflammation compared to SGPT.

This retrospective study research showed that there were 12 patients who experienced an increase in SGPT scores after receiving methotrexate therapy. Statistical analysis were showed p value = 0.001 which shows that there is a statistically meaningful difference in the increase in SGPT scores before and after receiving methotrexate therapy. It is explained in the study that liver injury is most often assessed through liver enzymes, namely SGPT which increases in 7.5-26% of all patients treated with MTX depending on the cut-off rate used.¹⁹ Increased SGPT during methotrexate therapy supports a multifactorial background of liver toxicity. A study

identified SGPT elevations found before the start of MTX therapy as the strongest predictors for SGPT elevation during MTX therapy. Elevation of SGPT values prior to the start of MTX therapy was found in 20 of 84 patients (24%), and all experienced repeated increases in SGPT during MTX therapy.²⁰ Enzyme SGPT is mainly found in the hepatocyte cytoplasm, and increases during liver damage involving the cytoplasm. Therefore, methotrexate may have injured the hepatocyte cytoplasm resulting in a significant increase in SGPT activity.²¹ Liver toxicity is a major health problem of worldwide proportions. The hepatoprotective activity is confirmed by decreasing the activity of serum enzymes, SGOT, SGPT, Bilirubin, Cholesterol, while it significantly increased the reduced protein levels in dose dependant manner.²² A combination of methotrexate with biologics works synergistically leads to an improvement in their clinical efficacy, methotrexate tolerability and also suppresses the immunogenicity of these agents and increasing their serum drug levels.²³

From this retrospective study we can concluded there was significant decrease in PASI scores and significant increase in SGPT scores before and after receiving methotrexate therapy. However, for SGOT scores statistically there was no significant difference before and after receiving methotrexate therapy.

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SURAT EXEMPTION
(“ LETTER OF EXEMPTION ”)

Ref. No. : 0684/LOE/301.4.2/XI/2021

Judul Protokol Penelitian : EVALUASI EFIKASI DAN EFEK SAMPING GANGGUAN FUNGSI HATI
PASIEN PSORIASIS VULGARIS YANG MENDAPAT TERAPI
METHOTREXATE DI RSUD DR. SOETOMO SURABAYA

Dokumen yang disetujui : 1069/112/4/X/2021 (versi: 3)

Tanggal terbit : 12 November 2021

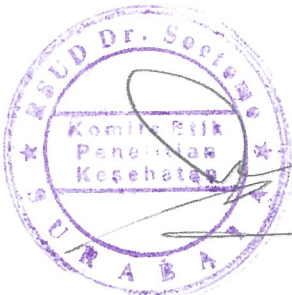
Berlaku sampai : 12 November 2022

Peneliti Utama : Prof. Dr. Cita Rosita Sigit Prakoeswa, dr., Sp.KK (K)

Peneliti Lain : 1. Dr. Afif Nurul Hidayati, dr., Sp.KK (K)
2. Ira Yunita, dr

Instalasi/Tempat Penelitian : RSUD Dr. Soetomo

Komite Etik Penelitian Kesehatan RSUD Dr Soetomo menyatakan bahwa dokumen diatas sesuai dengan The Office for Human Research Protections (OHRP) dibawah persyaratan the U.S. Department of Health and Human Services (HHS) Regulasi 45 CFR bagian 46 untuk **exempt review**.



Prof. Dr. Hendy Hendarto dr., SpOG(K)
Ketua Panel 1

Dra. Siti Farida SpFRS, Apt
Sekretaris Panel 1