ROFEL Shri G M Bilakhia College of Pharmacy

Experience Innovation in Education

Approved by Pharmacy Council of India (PCI) and Affiliated to GUJARAT TECHNOLOGICAL UNIVERSITY (GTU), AHMEDABAD

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Our Highlight of Month

વાપી રોફેલ ફાર્મસી કોલેજનું ૧૦૦ ટકા પરિણામ

વાપી : ગુજરાત ટેક્નોલોજિકલ યુનિવર્સિટી અમદાવાદ દ્વારા મે-૨૦૨૧માં લેવાયેલી બી.ફાર્મ. સેમેસ્ટર-૦૬ની પરીક્ષાનું પરિણામ જાહેર થતા રોફેલ શ્રી જી.એમ. બિલખીયા કોલેજ ઓફ ફાર્મસી વાપીની વિદ્યાર્થિનીએ જીટીયુ ટોપટેનમાં સ્થાન મેળવી કોલેજ તેમજ વાપીને ગૌરવ અપાવ્યું છે. બોદાલીઆ સલોની ધર્મેન્દ્રભાઈએ જીટીયુ ટોપટેનમાં ૯.૭૨ (સીજીપીએ) મેળવી સમગ્ર રાજ્યમાં આઠમો ક્રમ પ્રાપ્ત કર્યો છે. આ પરિણામમાં કોલેજના ૧૦૦ ટકા પરિણામ સાથે ૯૬.૭૭ ટકા વિદ્યાર્થીઓએ ૧૦માંથી ૭ એસપીઆઈ કરતા વધુ મેળવી કોલેજને ઝળહળતી સિદ્ધિ પ્રાપ્ત કરી છે. જે સિદ્ધિ બદલ વિદ્યાર્થીને અરિન્દમ પાલ, સમસ્ત ટ્રસ્ટીગણ તથા સ્ટાફ મિત્રોએ અભિનંદન પાઠવ્યા હતા.

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INSTITUTE AFFAIRS

THE SONGS OF MEGHANI EVENT

On the occasion of 125th Birthday of SHRI ZAVERCHAND KALIDAS MEGHANI, the students of ROFEL Shri G. M. Bilakhia college of Pharmacy celebrated this occasion by memorizing his songs. A competition entitled "THE SONGS OF MEGHANI" was organised by the cultural team of the college on 2nd September 2021, in collaboration with Gujarat Technological University, Ahmedabad in which students of B.Pharm Sem3 , 5 & 7 participated by reciting poem and singing the famous song creativities of Shri Zaverchand Meghani.The best entries were declared as winners who also get opportunity to participate at the university level for the same competition.

Students singing songs and reciting poem of Shri Zaverchan Meghani

WORLD PHARMACIST DAY CELEBRATION

Our Institute celebrated "World Pharmacist Day" as on 25th September, 2021 under guidance of Principal of the institute Dr. Arindam Paul. Various events were organized for future pharmacist of our institute. Considering the theme of the World Pharmacist Day – 2021 "Pharmacy: Always Trusted for your health", An Essay Competition was held on the same topic. A Quiz competition was also held for the students by using technological aids (google form). Students of B.Pharm Semester 3, 5, and 7 participated in those events and showed their views as a part of their future responsibilities as a pharmacist with great enthusiasm. All the participants were felicitated with E-certificate and The best performing students were declared as winners.

Students participating in Essay competition

Brochure shared with students for THE WORLD PHARMACIST DAY 2021 celebration

TEACHERS DAY CELEBRATION

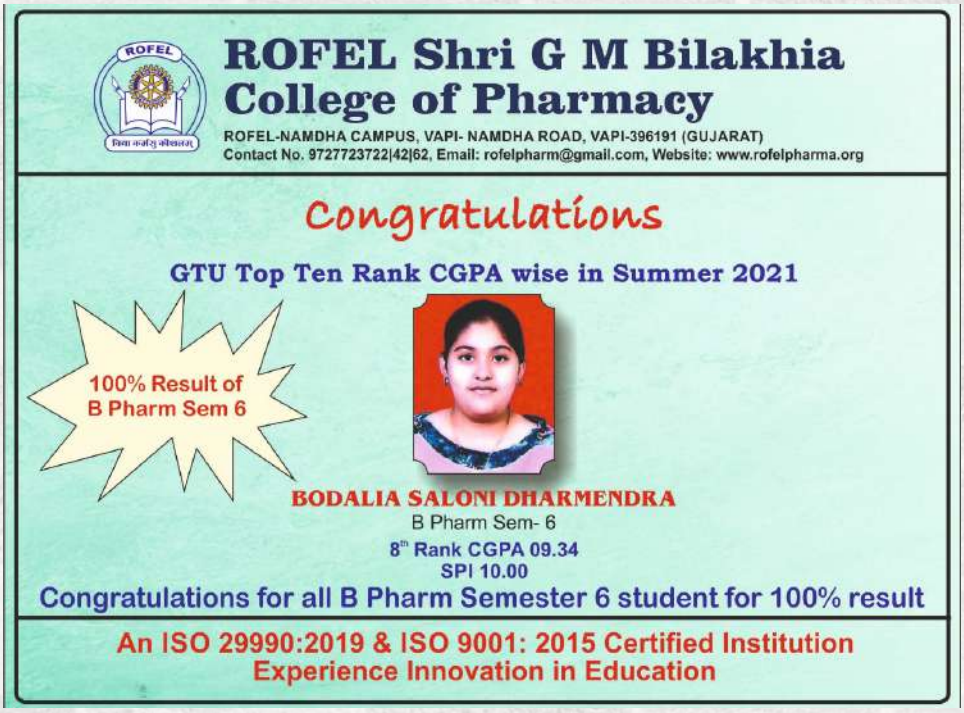
On the Occasion of birth anniversary of a great teacher Dr Sarvepalli Radhakrishnan, 5th September is celebrated as TEACHER'S DAY of India since 1962. The students of ROFEL Shri G. M. Bilakhia college of Pharmacy also celebrated this day on 6th September 2021 in honour of all the faculties and other staff members of the college. The senior students of B.pharm & M.pharm took responsibilities of teaching by taking lectures and practical of the junior students of B.pharm in order to show their appreciation for the faculties. A small function was also arranged by the students for honouring the teachers of the college. All the teachers were warmly welcomed with flowers by the students. The programme was followed by various activities by students like dance, singing, Skit, games for teacher's and speech which were framed on the theme of Teacher's day.

Speech by Dr. Arindam Paul | Floral welcome of teachers | Students conducting event

Games | Dance | Skit

Dance | Poem for teachers | Melodious songs

STUDENT AFFAIRS



Student of B.Pharm 6th Sem Ms.Saloni Bodalia secured GTU Top Ten Rank in Summer 2021 Exam.

Student of B.Pharm 6th sem secured 100% Result in Summer 2021 Exam.

Pharma Games

Guess the Name of Medicine with the help of Emoji

Answers

1. Penicilllin
2. Tigecycline
3. Monurol
4. Vancomycin
5. Doxycycline

PHARMA TALKS

Is India's pharma sector being penalised for its success?

India Pharma Inc was in for a rude shock on August 17 when the Government of India finally announced the rates of rebate under the Remission of Duties and Taxes on Exported Products (RoDTEP) scheme.

The pharma sector, along with chemicals and steel, has been left out of RoDTEP, which would be effective from January 01, 2021. Ostensibly, because India enjoys global competitiveness in these sectors, but it is more likely that the government would like to discourage or at least not do anything to make exports easier in sectors where there is a short supply in the domestic market.

And the pharma sector certainly meets this description. A case in point is COVID vaccines, where output still does not meet demand. Beyond vaccines, the government is currently engaging all stakeholders to create and maintain a pool of essential medicines and medical products to prepare for future waves. Clearly, the message seems to be that managing the COVID-19 situation in India takes precedence over exports.

Industry associations like the Indian Pharmaceutical Alliance (IPA) have registered their protest. Sudarshan Jain, Secretary-General, IPA asserts that the pharma industry deserves three to six per cent benefit both for API and formulations. The IPA has emphasised this point to the relevant committee, says Jain.

The IPA's contention is that the exclusion of pharma exports from the RoDTEP scheme will adversely impact the pharma sector's competitiveness, depriving pharma exporters of a level playing field vis-a-vis global manufacturers.

Jain points out that competition is increasing from various countries and it is important to provide a level playing field to the sector to maintain a competitive position and leverage the potential of the industry.

The IPA statement alludes to the highly regulated nature of the sector and the need for huge capital investment to set up manufacturing infrastructure. In fact, the IPA argues that 'for sustaining India's export competitiveness, RoDTEP benefits should be extended to the pharma sector given the importance of the sector in access of affordable medicine to patients in India and around the world.'

It follows that pharma exports set off the costs of providing affordable medicines in India. Seen in that light, it would make sense to extend the RoDTEP scheme to the sector, but the government is evidently worried that medicines and vaccines meant for India will be diverted to exports.

Leaving out pharma from the RoDTEP scheme is harsh but the message is that managing the COVID-19 situation in India takes precedence over exports

The country's COVID vaccine coverage is still low. According to the Our World in Data site, as of August 24, 2021, just 9.42 per cent of India's population has had two doses, while 23.35 per cent have had a single dose. With just 32.77 per cent of our population vaccinated with one or two doses, talk of a third booster dose seems counterintuitive.

So will the government consider the industry's argument, given that exports have been a high thrust area? As IPA's Jain points out, the RoDTEP policy has a significant impact on Indian pharma's export performance. The Government has planned an increase in exports to $400 billion by the end of the financial year from the current level of $300 billion, which would make it an increase from 10 per cent to 15 per cent of GDP by the end of the decade.

Pharma will play an important role in the growth journey, explains Jain, with pharma exports expected to grow from $24 billion to $29 billion this year and to $75 billion by the end of the decade. But to achieve this, "All-round policy support will be important to harness the potential of the industry in the highly competitive and changing global landscape," says the IPA chief.

India Pharma/Vaccine Inc, like its global peers, is looking at the COVID pandemic as both an opportunity to meet an unmet medical need as well as claim a slice of the COVID pie and gain market share. This is to be expected, after all, these companies have to also answer to their shareholders.

And the government too would like to prove India's prowess in vaccine development with exports to countries that do not have this infrastructure yet. In fact, NK Arora, Chairman of the National Technical Advisory Group on Immunization in India has clarified that exports of COVID-19 vaccines from India will resume in 2022, once all adult Indians are fully vaccinated.

This is going to be a multi-year battle against the coronavirus, which requires both industry and government to align together. Thus the pharma sector might have to forgo the benefits of the RoDTEP scheme, keeping in mind the larger picture.

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Novel drug delivery systems offer a unique challenge for conducting meaningful dissolution. Custom made dissolution methodologies help in performing dissolution testing of these sophisticated products.

Nanocarriers offer similar challenges during dissolution, be it SNEDDS, liposomes, SLN or polymeric nanoparticles

Selection of best dissolution method for a nanocarrier-based system

Dissolution methods for nanocarrier based systems need to address the critical aspect of nanocarrier size, a unique feature that differentiates nanocarrier based systems from other systems. Accordingly, there are two basic options. The sample and separate method and the dialysis sac or membrane methods. In the first method separation of the nanoparticles from the sample aliquot is the major challenge. Further, this method is generally relied on only when the use of a dialysis membrane poses constraints.

The dialysis methods are gaining popularity and acceptance. Nevertheless, it is important to ensure that the method provides good reproducibility, is discriminating and is easy to handle. Our experience in working on USP I, USP II and USP IV proposes the USP IV or flow-through cell apparatus, with a ready to use dialysis adapter (Floatalyzer) as a practical method for nanocarrier based systems.

Recommendations for developing a dissolution method for SNEDDS

Nanocarriers generally offer similar challenges during dissolution, be it SNEDDS, liposomes, SLN, polymeric nanoparticles etc. This challenge is generally related to their size. Nevertheless, lipid-based formulations like SNEDDS and SMEDDS due t the lipidic contents could a fect the permeability of th dialysis membrane to creat artefacts. One approach is t dilute the formulation as muc as possible for the dissolutio test, to minimise such effect Another option is to use a dia ysis membrane with a molecu lar weight cutoff much greate than the suggested 10 fold cu off. If both options are n found effective one must re on the sample and separat method, with an effective ap proach for separation whic could be ultracentrifugation syringe filtration through ap propriate filters, ultrafiltratio or maybe even pressur filtration.

Prof Padma V Devarajan, Dean, Research and Innovation, Professor in Pharmacy and former Head, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Mumbai

Material properties of the medicines and formulation strategies are critical for achieving their optimal dissolution and performance. One session was dedicated to these aspects and covered the following important topics:

Determination of bioequivalence is the biggest barrier towards development of topical and ophthalmic generic drug products

Challenges in developing generic products for topical and ophthalmic products

A generic drug product is a copy of a reference drug product and is chemically identical to its branded counterpart. The generic drug product is pharmaceutically equivalent and bioequivalent and is therapeutically equivalent to brand name product. Determination of bioequivalence is the biggest barrier towards the development of topical and ophthalmic generic drug products.

USFDA initiatives to accelerate entry of topical generics into the market

The FDA is conducting and sponsoring research to develop and identify in vitro and in vivo methods to determine the bioequivalence of topical drug products.

The research includes:

- Assessing new analytical methods for characterising complex formulations
- Developing in vitro release testing methods and exploring in vitro-in vivo correlations
- Developing in vivo bioequivalence methods using open flow micro-perfusion and dermal microdialysis
- Skin pharmacokinetic methodology for topical drugs using non-invasive techniques such as Raman microscopy
- Developing in vitro bioequivalence methodology
- Developing modelling and simulation methods to support in vitro bioequivalence evaluation (PBPK Modeling)

FDA is regularly publishing Product-Specific Guidances to help the industry develop generic drug products. In addition, FDA has established "Center for Research on Complex Generics" to help in developing and educating stakeholders in the area of complex generics.

Dr Vinod P Shah, Pharmaceutical Consultant, North Potomac, MD USA

Reference:India's Foremost Pharma & Biotech Magazine, Vol 16 No 12, September 2021