



SHRI B.V. PATEL ESSAY COMPETITION - 2024

Shri B. V. Patel Education Trust (REG. NO. E-2571, AHMEDABAD) invites entries for the essay competition for the year 2024. The subject for the essay is –

"Under estimated importance of Impurity profile in API - Serious threat and resultant consequences"

Chemical synthesis no matter whether it is in a small R&D setup or in a large manufacturing unit, always results in synthesis related undesirable product/s along with main product. This undesirable product/s along with main product may or may not matter much for chemistry but in pharmacy it may result in serious implications on consumers health in the form of side effects, toxicity / genotoxicity, deformity etc. These unwanted products along with the main product are known as impurities in pharmaceutical field.

"In the field of drugs and APIs, an impurity is considered as any other organic material, besides the drug substance, or ingredients, arise out of synthesis or unwanted chemicals that remains with Active Pharmaceutical Ingredients (API's)"

As per the International Council for Harmonisation (ICH) guidelines "Impurities are substances in the product that are not the Active Pharmaceutical Ingredients (API) itself or the excipient used to manufacture it"

API and drug product impurities can be crystallization related, stereochemistry related, residual solvent related, synthetic by product related and intermediate related. Impurities can also be arisen due to degradation, improper storage, cross interaction among ingredients and also functional group and shelf life related. Thus, effective management, identification and characterization of these impurities are essential to ensure that the final products adhere to regulatory guidelines and are safe for use or consumption

Impurity profiling refers to the systematic identification, characterization, and quantification of identified and unidentified impurities present in a drug substance or drug product

Underestimating the importance of the impurity profile in APIs can lead to serious threats and consequences throughout the pharmaceutical manufacturing process and beyond. It can lead to compromised safety and efficacy of final product, It can lead to failure of regulatory compliance, hinder process control due to degradation and incomplete reaction, reduce stability and shelf life cost implications and most importantly adverse effect on public health.

Impurity profile of an API is not just a technical detail but a critical factor that impacts patient safety, regulatory compliance, manufacturing efficiency, and overall success in the pharmaceutical industry. Therefore, careful attention to impurity profiles throughout the drug development and manufacturing lifecycle is essential

In this view the essay is expected to cover under estimated importance of Impurity profile in API - Serious threat and resultant consequences.

CRITERIA OF ELIGIBILITY

- 1) Any person interested in Pharmacy is entitled to participate in the competition.
- 2) Not more than two Figures may be appended with the essay. The text part of the essay including Tables should not **exceed 5000** words. Beyond 5000 words, it would attract minus marks. The essay **exceeding 6000 words** would not be eligible for competition.
- 3) A 300 word synopsis should also be accompanied with Essay.
- 4) Only **single** author entry shall be permitted. Acknowledgment of any significant advice or help from others may be made in the cover letter.
- 5) Acknowledgment or the name and address of the author **should not appear anywhere** on the body of the **essay** or on the **synopsis**.
- 6) The **last date** for the receipt of Essay is **September 30, 2024**. The essays received after last date will not be eligible for competition.
- 7) The essay should be exclusively written and submitted for this competition only. A certificate of plagiarism report should also be attached at the end of the essay. Plagiarism should not be more than 5% excluding references if any.
- 8) Gold medal winners of past year's Shri B.V. Patel Essay Competition are requested not to participate in this competition.
- 9) The decision regarding acceptance, rejection and the award of the medals for the essay would be solely of the Trust and abiding to all the participants.

AWARDS

First and Second prize winners will be awarded the **Gold & Silver Medal and a cash Prize of Rs. 31,000/- and 21,000/- respectively**, during 74th Indian Pharmaceutical Congress (IPC). Medal winning entries should be of at least **“Distinction (More than 70% score)”** quality as judged by the panel of judges.

HOW TO PARTICIPATE

Essay should be submitted in word format as well as PDF as single file in the sequence given here- (1) cover letter having author's name, address and contact details, (2) synopsis, (3) essay, (4) plagiarism certificate. The essay entries should be sent to administration@bvpedutrust.com or deputydirector@bvpedutrust.com. Subject line of the mail should be 'ESSAY COMPETITION -2024'. For more information please

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