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## Process Analytical Technology (PAT): An ideal or an achievable option for quality assurance?

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Process Analytical Technology (PAT) began with an initiative of the Food and Drug Administration (FDA) in USA, during its Science Board Meetings of 11/01 and 4/02. Science Board supported for FDA's proposal to facilitate innovation in the field of pharmaceutical manufacturing. This decision was materialized by a guideline "PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance" released in September 2004. The aim of this guideline is to encourage industrials to innovate "voluntarily" in manufacturing and to give them a guarantee of regulatory approval. PAT refers commonly to a system for designing, analyzing, and controlling manufacturing by timely measurements of critical quality and performance attributes of raw and in-process materials. It suggests the possibility of real time release of final products batches. In this work, we focus on the PAT tools for design, data acquisition and analysis, and on the feasibility of implementing these tools in a pharmaceutical plant to improve the level of quality assurance.

### Biography

Yacine Sellam has obtained his Pharm.D. at the age of 23 years from Algiers' University and he is now a postgraduate student in Analytical Chemistry Applied to Pharmaceutical Products at the same university. He is also a permanent Oncology Pharmacist at the Pierre and Marie Curie Center of Algiers. He has communicated in many regional symposiums and conferences on pharmaceutical quality assurance and regulatory affairs.

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## Formulation and evaluation of topical antifungal gel of Canarium strictum

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Fungal diseases that occur on the nails, hair, skin, and mucous membrane are referred to as superficial mycoses. Many of these fungi cause various forms of ringworm, or tinea, and the organisms that cause them are commonly called the dermatophytes, or ringworm fungi. Usually there is irritation, erythema, edema, and inflammation at the spreading edge. So, the present study deals with the formulation and evaluation of antifungal gel of Canarium Strictum. Gels are of two component semisolid systems rich in liquids. Their one characteristic feature is the presence of continuous structure providing solid like properties. Experimental work deals with the extraction of resin followed by phytochemical screening which shows positive results for triterpenoids. Two compounds were isolated from Canarium Strictum by counter current distribution phenomenon and illucidetd by IR. NMR and Mass spectroscopy. An antimicrobial study shows that the compounds possess broad spectrum antimicrobial activity at concentration of 10µg/ml. Three formulae for gel were tried amongst which formula 1 shows smooth texture, optimum pH and good spreadability and hence optimized. The appearance, viscosity and spreadability of the gel at various temperatures did not change. Hence, gel has good stability. Drug diffusion study of formulation was also done and the drug release was evaluated and determined by using TLC. From the results the gel formulation was finalised and found effective to treat fungal infection.

### Biography

Mr. Vikas P. Gabhane has completed Bachelor of Pharmacy from Agnihotri college of Pharmacy, Wardha and currently persuing Masters of Pharmacy from Sharad Pawar college of Pharmacy, Nagpur. He attended three national conferences and passed certificate course in Regulatory Affairs (RA) from Institute of Management Studies and Research (IMSR), Nagpur.

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