

## Stereoselective syntheses of naturally occurring 20-epi cholanic acid derivatives and other bioactive compounds from 16 dehydropregnenolone acetate

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A wide variety of diterpenes, sesquiterpenes and steroids have been reported to have modified isooctyl (cholesterol-type) side chains and the unit being attached to the polycyclic nucleus at C-17 with (R) or (S) stereochemistry at C-20. The introduction of the properly functionalized side chains onto tetracyclic steroidal starting materials has been the subject matter of several investigations. An important problem that arises in this approach is the stereoselective control of the C-20 stereochemistry. These efforts have been spurred by the biological significance of new natural products containing modified side chains and synthetic endeavors towards a variety of vitamin D metabolites, brassinosteroids, squalamine, OSW-1, ent-steroids and various marine steroids. We have reported the synthesis of C(20R) aldehydes by ionic hydrogenation of C-20, 22-ketene dithioacetal and C-20 tertiary alcohols with 100% stereoselectivity. In continuation of this and other work, we wish to report here the stereoselective synthesis and ionic hydrogenation of various steroidal C-20 tertiary alcohols to the corresponding steroid derivatives with natural and unnatural configuration at C-20. Elaboration of the synthesized intermediates to biologically active compounds will be discussed.

### Biography

Bapurao B. Shingate has obtained B.Sc and M.Sc. degrees from Dr. Babasaheb Ambedkar Marathwada University, Aurangabad (MS), India. He did his Ph.D degree in 2010 from University of Pune, Pune (MS) under the supervision of Dr. Braja G. Hazra at Division of Organic Chemistry, National Chemical Laboratory (CSIR), Pune. His Ph.D work focused on the stereoselective syntheses of steroidal unnatural C(20R) aldehydes by ionic hydrogenation and their elaboration to naturally occurring 20-epi cholanic acid derivatives. His current research interests include asymmetric synthesis, total synthesis of natural products, multi-component reactions, heterocyclic synthesis and green chemistry. He has published about 50 research articles in the journals of international repute and written 1 chapter of a book.

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## Regulatory status of biosimilar medicinal products in Europe and USA

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When a biopharmaceutical product patent expires, other manufacturers can produce copies of the original drug. These products, called biosimilars are similar but not identical to the innovator drug due to the protein nature complexity. Biosimilars, unlike chemical synthesis generics, can only obtain a marketing approval at European level through a centralized procedure overviewed by the European Medicines Agency (EMA). In order to test the efficacy, safety and quality of biosimilars, the EMA has established several mandatory guidelines that will be discussed. The current situation at USA will also be analyzed as well as the harmonization perspectives at global level.

### Biography

Begoña Calvo at present is Professor at the Department of Pharmaceutical Technology, University of the Basque Country (Spain). She earned her Ph.D. from University of Salamanca (Spain) and Post-doctorate from Mario Negri Institute for Pharmacological Research (Italy). She has published and presented more than eighty original research papers, articles and abstracts in peer reviewed journals and conferences. Her main scientific areas of research are Experimental and Clinical Pharmacokinetics as well as the Regulatory basis of biopharmaceuticals. He serves as reviewer for more than 20 scientific international journals.

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