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QUANTITATIVE ESTIMATION OF POLYPHENOLIC AND STEROLS CONTENT IN BOMBAX CEIBA FLOWERS EXTRACTS

Lekurwale A.S, Warokar. A, Mahajan .U

Dadasaheb Balpande College of Pharmacy, Besa, Nagpur, Maharashtra-440037. ashishlekurwale5@gmail.com

ABSTRACT

The present investigation deals with standardization of Bombax ceibaflowers extracts by quantitative estimation of its secondary metabolites. To determine total polyphenolics, flavonoids and sterols content in Bombax ceiba flowers extracts. Bombax ceiba flowers were successively extracted by nonpolar to polar solvents. The preliminary phytochemical screening and TLC fingerprinting of Bombax ceiba flowers extracts were evaluated to determine the nature of phytoconstituents. Total polyphenolic content were evaluated by Folin–Ciocalteu method while total flavonoids content were evaluated by aluminum chloride colorimetric method. Total sterols content were evaluated by Liebermann–Burchard reagent. The preliminary phytochemical screening revealed the presence of sterols, tannins, flavonoids, sugars, and triterpenes. Total polyphenolic content of ethyl acetate and methanolic extract was found to be 27.82 ± 0.88 and 21.13 ± 0.31 mg/g of GAE respectively. Total flavonoid content of ethyl acetate and methanol extract was found to be 23.88 ± 0.32 ug/gand 40.79 ± 0.44 ug/g respectively relative to standard quercetin. Total sterol content of ethyl acetate, petroleum ether and methanol extract was found to be 17.81 ± 0.38 ug/g, 30.25 ± 0.33 ug/g and 35.75 ± 0.96 ug/g of cholesterol respectively. The above results demonstrate that the extracts of Bombax ceiba exhibits high content of bioactive constituents like flavonoids, sterols.

Keywords Polyphenolic, TLC fingerprinting, Flavonoids

PHARMACOVIGILANCE OF BIOSIMILARS CONSIDERATION NEED AND CHALLENGES Raut P. S. and Chakolkar M. D.

Rajarshi Shahu College of Pharmacy, Malvihir, Botha Road, Buldana, Maharastra 443001 India poojaraut43359@gmail.com

ABSTRACT

The generic pharmaceuticals, it is impossible to generate the same or identical copy product. In this way, biosimilars are "similar but not the same" or in other word are "the twin but not the clone" to the original biologic innovator product. The biosimilars presents several challenges like verification, interchangeability of biosimilars and innovator products and possible naming to differentiate the various biopharmaceutical products. The market is constantly increasing, and several biosimilars are being used, while many are still waiting to become available to the public. Biosimilars are more complex than generics, and regulatory agencies have very stringent criteria for approval. Risk management applies scientifically based methodologies to identify, assess, communicate and minimise risk throughout a drug's life cycle so as to establish and maintain a favourable benet-risk prone in patients. The risk management plan for biosimilars should focus on heightens the pharmacovigilance measures, identify immunogenicity risk and implement special post-marketing surveillance. Pharmacovigilance of biologics should include processes that are easily used by prescribing practitioners to ensure that data are consistent and new safety signals are properly reported and assigned to the correct product. pharmacovigilance system that can accurately trace biologics, including biosimilars and their reference products, from the patient to the manufacturer.

Keywords Generic, Biosimilars, Pharmacovigilance.