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Ethanol content in traditionally fermented ayurvedic formulations has compromised good manufacturing practice regulations-compromised health

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A large part of the population of India prefers the traditional medicine for primary healthcare. However, the effective quality control of herbal medicine is still a big challenge. Numerous reports indicate noncompliance with good manufacturing practice (GMP) guidelines by the manufacturers which may lead to adverse drug reactions or toxic effects. Asava and arishta are the classical herbal dosage forms wherein fermentation occurs during production leading to the generation of ethanol. The presence of ethanol in these preparations may lead to their abuse for the pleasure and enjoyment. The self-generated ethanol is responsible for extraction of active constituents and acts as self-preservative. As the procedure for preparation for asava and arishta is same, the ethanol content is also expected to be the same irrespective of the manufacturer. The objective of the present study was to assess and compare the ethanol content of some traditionally fermented ayurvedic formulations available in the market. Method in this study include 20 formulations from 3 different manufacturers available as over-the-counter (OTC) product were obtained and their ethanol contents were determined using gas chromatograph (GC) fitted with flame ionization detector (FID). Statistically significant differences were noted in the ethanol content of various formulations. A simple, less time consuming, economic and validated gas chromatographic method for estimation of ethanol in fermented ayurvedic formulations was also developed successfully in present study. The data generated during study reflected poor compliance of GMP guidelines by the manufacturers and hence the quality is being grossly compromised posing a safety hazard.

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