Halal Pharmaceutical Ingredients Standards for the Built-in Concept

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ABSTRACT

Modern medicines are formulated from pharmaceutical ingredients fulfilling the established quality, safety and efficacy parameters as compiled and documented in monographs of the pharmacopoeia. The criteria on halal are not accounted for and therefore their halal status is questionable. Our research shows that utilization of porcine and animal based materials is commonly used in current pharmaceuticals. The Malaysian Standards MS 2424: 2019 Halal Pharmaceuticals - General Requirements was established to address the halal issues and currently being used by the industry related to pharmaceuticals, nutraceuticals, supplements, vaccines and herbal medicines. Being an important guide for halal manufacturing, the vital component that is lacking and not addressed is the standard for halal ingredients namely the halal pharmacopoeia. In the absence of this document, no halal auditing for this industry sector is possible as the main referral document and materials are unavailable. To overcome this problem, the establishment of the Halal Pharmacopoeia is imperative. To ease the classification of ingredients entries, the color code is introduced as green (halal), red (haram) and grey (masbooh). Our initial findings from selected major pharmacopoeia have showed that lest than 10% of the ingredients entries are in the red and grey list, whilst the majority 90% is considered green. In the halal built-in concept also known halal by design, to incorporate the halalan toyyiban (HT) value system, the application of halal in manufactured products requires the understanding of the origin and how the products are made and how halal can be established, produced and sustained in its production. The US FDA have emphasized the concept of "quality built-in rather than tested for" to be applied in the highly regulated pharmaceutical sector; a philosophy that is highly tenable and applicable in an industry faced with serious quality issues relating to adulteration and non conformance to established standards. In the pharmaceutical and related industries, formulated ingredients normally consists of active pharmaceutical ingredients (API), excipients, colorants, stabilizers, processing aids etc. Following Good Manufacturing Practices (GMP) requirement, all ingredients shall be checked and confirmed qualitatively and quantitatively, followed by the formulation process and then packed with quality packaging materials into suitable dosage forms and thus ending as a quality built-in product. There is no necessity to analyze quality in the final product if the manufacturer conforms to the specifications and regulations as stipulated in the pharmacopoeia standard documents.