

Development of Marker Compounds

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The inclination of going back to natural world spreads throughout the world, which has encouraged in the development of therapeutically active compounds. Various chemical compounds which are considered as active pharmaceutical ingredient contain only single chemical component however extracts derived from botanicals contain large number of chemical components. This raises a serious concern in their quality assurance. Due to availability of modern chromatographic techniques and various analytical tools in pharmaceuticals sciences it's now possible to characterize and quantify the chemical constituents in botanical drugs. Generic way to define a marker compound is that it's a pure and valuable i.e. may or may not be therapeutic active and commercially important chemical which can be utilized as standard or reference compound to confirm its natural existence in terms of potency or identity. These marker compounds can be utilized as an intermediate compound and also to identify and quantify the presence of same compounds in nature. Development of marker compound involves extraction, isolation and characterization of chemical compounds by using suitable extraction, chromatographic and spectroscopic techniques. Chromatographic fingerprinting by HPTLC offers chromatographic pattern of the extract. This pattern usually represents all therapeutically active chemical compounds by means of which confirmation and identification of natural products can be precisely conducted. These herbal reference compounds are used as reference standards which are characterized by means of identity and purity testing as per international guidelines (WHO, 1999) against samples. European Pharmacopoeia and United States Pharmacopoeia offers standard information related with herbal reference standards. Development of new marker compound and its certification is still a challenge for regulatory and manufacturer. As per WHO guidelines certified reference substances are reference substances which are certified by regulatory bodies whereas marker substances are reference substances that are may or may not be therapeutically active but all are chemically defined components of a plant material.

There is different class of International Chemical Reference Substances (ICRS) reference substances. These substances are developed by WHO Expert Committee. Thus, various pharmacopoeial authorities assist interested organizations in developing marker compounds as the standard guidelines. Expense involved in the development of marker compound and expense of marker itself is still matter of concern however various economic strategies can be developed to cut down the cost and time. Yield of marker compounds is again matter of concern which can be overcome by using plant tissue culture science. Intent of this section is to demonstrate journey of marker from extract by chromatographic fingerprinting to develop certified standard reference marker to make consistent herbal drug products.

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