SUGGESTIONS RELATIVE TO STANDARDS AND METHODS OF ANALYSIS.

L. F. KEBLER, CHIEF OF DRUG DIVISION, BUREAU OF CHEMISTRY.

The work during the past few years has shown the great need of more concerted cooperative and fundamental investigations. There has been a dearth of available workers. There is a great need of studying analytical methods with a view of determining what degree of accuracy can be obtained by workers either in the same or different laboratories. The Pharmacopæia prescribes specific standards for certain drugs and indicates standards for others. In many instances these specific standards have been found wanting; for example, the standard for cannabis indica states specifically that the powder shall contain few or no stone cells, which means a virtual absence of seeds. In practice it has been found exceedingly difficult to put this standard in force for the simple reason that very few samples available on the market are free of seeds to the extent prescribed. Furthermore, information is lacking as to just what amount of seed should or should not be permitted.

Another feature is that certain of the methods do not give satisfactorily concurrent results in the hands of different workers; for example, the method prescribed for determining the alkaloidal matter in hyoscyamus is liable to a variation of 100 percent in the hands of different workers, and naturally with such a great variation as this it would be difficult to use the method to advantage. The chief difficulty with the method appears to be insufficient time and solvent to properly extract the alkaloidal material from the powdered plant. Similar difficulties of the above character can be referred to, but these are sufficient to indicate the shortcomings of certain prescribed standards.

Attention is now called to the standards that are indicated but not specifically prescribed. Such standards, for example, as to the amount of alcohol present in a finished product made according to prescribed formula, or the amount of extractive or other factor that may contribute to the value of determining the quality of the commodity. For example, the Pharmacopoeia prescribes a method for manufacturing tincture of capsicum, but no definite statement appears as to the amount of alcohol that should be present in the finished product. Neither is there any reference made as to the amount of matter that might possibly be present in a preparation made as directed by this authority. This feature is a most important one, because it is well known that alcohol (95 percent) in many instances extracts far less material than does a solvent containing more water. This feature is recognized by most manufacturers and taken advantage of.

In a paper communicated to the Association of Official Agricultural Chemists last year by Mr. Street on the subject of ginger extracts, attention was called to the fact that menstrua containing smaller amount of alcohol than that contained in the ordinary alcohol removed considerable more extractive matter than does 95 percent alcohol. The writer has conducted experiments on tincture of ginger which corroborate the findings of Mr. Street in this particular.

In this connection it might be well to call attention to the well-known fact that the examination and investigation of food and drug problems frequently overlap each other, and if it were possible to arrive at some plan whereby the efforts of the investigators of subjects that have to a certain extent a common basis could be correlated, it certainly would be most desirable. Such a plan would eliminate so-called double standards in many instances.

Many of the present standards for crude drugs make no provisions whatever for the presence of certain incidental or accidental foreign material that is usually present in these products. In the past such foreign material has constituted a goodly percentage of the product; for example, uva ursi has been offered for import containing in excess of 40 percent of stems, foreign material, worthless leaves, etc. The excuse offered by the importer for the character of the product was that the commodity is intended to be used in the manufacture of cattle powder or veterinary remedies. Steps have been taken to reduce the percentage of such foreign material imported. In fact, certain importations have been permitted to be released only on condition that the importer would eliminate excessive amount of foreign material. An excellent example where this requirement can be put into practice is the foreign material contained in cubeb berries. There is no excuse whatever for having in cubeb berries more than 5 percent of foreign material. Such foreign material as is commonly met with in this commodity can easily be eliminated by mechanical means. Experience has furthermore shown that it will be necessary to prohibit the importation of commodities containing excessive amount of foreign material, if it is expected to supply the pharmaceutical and medical professions with agents with which to treat the unfortunate sick to the best advantage. In the past certain goods have been released on condition that they be marked, indicating the nature and character of the impurities present, but it subsequently developed that these goods were supplied on orders without indicating to the purchaser that fact that the article was not of the proper character. Such transactions frequently resulted in the second dealer finding himself in conflict with the law. Furthermore, such goods are at times shipped into interstate commerce with the proper marking on same, but after they have entered the borders of a state the original package is broken and the consuming public is at the mercy of the dealers, unless state officials come to the rescue. It is hoped, therefore, that the state officers charged with the supervision of the enforcement of the drug laws will take an active interest in these matters.