

INTISARI

Eksipien merupakan salah satu bahan baku obat yang masih diimpor oleh Indonesia. Kemandirian eksipien dapat dimulai dengan memanfaatkan kekayaan alam Indonesia berupa pati atau amilum yang terbatas digunakan sebagai bahan pangan. Penelitian bertujuan untuk mengetahui kualitas amilum *oryzae food grade* dibandingkan dengan amilum *pharmaceutical grade* berdasarkan persyaratan Farmakope Indonesia dan USP-NF yang kemudian dikomparasikan untuk mengetahui gap kualitas antar amilum tersebut.

Kualitas amilum diketahui dengan melakukan karakterisasi sifat fisika, kimia, dan mikrobiologi amilum berdasarkan persyaratan Farmakope Indonesia dan USP-NF. Sampel berupa dua merk tepung beras *food grade* dan digunakan Amprotab sebagai amilum *pharmaceutical grade*. Data dianalisis dengan statistika deskriptif dan dikomparasikan secara deskriptif. Hasil analisis yang diperoleh berupa gap parameter antara amilum *oryzae food grade* dan amilum *pharmaceutical grade*.

Karakteristik fisika yang diuji adalah organoleptik, mikroskopik, ukuran partikel, pH, dan *bulk density*. Karakteristik kimia yang diuji adalah susut pengeringan dan sisa pemijaran. Karakteristik mikrobiologi yang diuji adalah Angka Lempeng Total, Angka Kapang Khamir, dan Angka Paling Mungkin Koliform. Hasil penelitian menunjukkan karakteristik fisika dan kimia amilum *oryzae food grade* memenuhi persyaratan Farmakope Indonesia dan USP-NF, sedangkan karakteristik mikrobiologi tidak memenuhi persyaratan. Gap kualitas amilum terletak pada parameter Angka Kapang Khamir dan Angka Paling Mungkin Koliform.

Kata kunci : amilum oryzae, food grade, pharmaceutical grade, komparasi

ABSTRACT

Excipients is one of the raw medicine material that still imported by Indonesia. The independence of excipients can be achieved by utilizing the natural source of Indonesia, such as amylum or starch which is limited used as food. The objective of the study was to find the quality of food grade amylum oryzae compared to the pharmaceutical grade amylum based on the requirements of Farmakope Indonesia and USP–NF, then compared to find the quality gap between these amylum.

The quality of amylum is known by characterizing the physical, chemical, and microbiology properties of amylum based on the requirements of Farmakope Indonesia and USP–NF. Samples are two brands of food grade rice starch and Amprotab is used as pharmaceutical grade amylum. Data were analyzed with descriptive statistics and compared descriptively. The results of the analysis are gap parameters between food grade amylum oryzae and pharmaceutical grade amylum.

Physical characteristics that tested were organoleptic, microscopic, particle size, pH, and bulk density. Chemical characteristics that tested were loss on drying and residue of ignition. Microbiological characteristics that tested were Total Microbial Count, Yeast and Mold Count, and Most Probable Number Coliform. The study showed that physical and chemical properties of food grade amylum oryzae meet the requirements of Farmakope Indonesia and USP–NF, while microbiological properties do not meet the requirements. The quality gap between food grade amylum oryzae and pharmaceutical grade amylum are in parameters Yeast Mold Count and Most Probable Number Coliform.

Keywords: *amylum oryzae, food grade, pharmaceutical grade, comparison*