Preparasi eksipien ko-proses maltodekstrinsuksinat, polivinil pirolidon dan manitol yang digunakan dalam formulasi tablet cepat hancur fraksi aktif buah oyong (luffa acutangula l) roxb) sebagai antisindrom metabolik = preparation of co process excipient of maltodextrinsuccinate polyvinyl pyrrolidone and mannitol in the formulation of orodispersible tablet containing the active fractions of luffa acutangula l roxb fruit as antimetabolic syndrome

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Abstrak

Tablet Cepat Hancur (TCH) telah dikembangkan bagi pasien yang sulit menelan tablet konvensional atau kapsul terutama untuk obat-obat yang mempunyai dosis besar seperti sediaan herbal. Ekstrak herbal umumnya mempunyai karakteristik lengket, higroskopis sehingga mempunyai flowabilitas dan kompresibilitas yang buruk, selain itu mempunyai rasa tidak enak dan dosis besar, karena itu dibutuhkan suatu metode dan eksipien yang dapat mengatasi karakteristik tersebut agar didapatkan TCH yang aman, berkhasiat dan disukai konsumen. Dilakukan penelitian pembuatan sediaan TCH dengan bahan aktif ekstrak buah oyong (Luffa acutangula (L) Roxb) yang hancur dan larut dengan cepat di saliva. Digunakan eksipen yang dibuat dengan cara ko-proses maltodekstrin suksinat (MDS), polivinilpirolidon (PVP) dan manitol (Mnt) rasio 1: 1: 8; 2: 1: 7 dan 3: 1: 6.

Massa TCH dibuat dengan 3 metode, yaitu eksipien tunggal ko-proses MDS, PVP dan Mnt ditambahkan ekstrak dan dilakukan spray drying (formula F1, F2, F3), eksipien ko-proses dikeringkan dengan spray dryer dan ekstrak ditambahkan secara fisik (formula F4, F5, F6), eksipien (tanpa ko-proses) dan ekstrak dicampur secara fisik (formula F7, F8, F9), kemudian masing-masing massa tablet dikempa, selanjutnya TCH yang dihasilkan dikarakterisasi dan dievaluasi. Terhadap TCH juga dilakukan uji stabilitas dipercepat, uji hedonik serta uji khasiat pada hewan coba. Fraksi aktif ekstrak buah oyong dilakukan uji antisindrom metabolik, uji toksisitas akut, skrining fitokimia dan standardisasi ekstrak.

Hasil penelitian menunjukan bahwa TCH formula F2 mempunyai performans sediaan tablet terbaik dan memenuhi karakteristik farmakope. Studi stabilitas dipercepat tidak terlihat adanya perubahan fisik, uji hedonik TCH F2 disukai oleh konsumen. Fraksi aktif ekstrak buah oyong terbukti berkhasiat sebagai antisindrom metabolik pada hewan coba, dikategorikan praktis tidak toksik dan memenuhi persyaratan standardisasi ekstrak. Senyawa Cucurbitacin diduga sebagai zat berkhasiat dalam buah oyong, berat molekul senyawa ini ditemukan dalam ekstrak dan serum darah hewan uji yang diberi TCH. Fraksi aktif buah oyong telah berhasil dibuat TCH menggunakan eksipien tunggal MDS-PVP-Mnt rasio 2:1:7 dengan metode koproses - spray drying dan dapat dijadikan alternatif antisindrom metabolik.
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Fast Disintegrating Tablet (FDT) has been developed for patients who have difficulty swallowing conventional tablets or capsules especially medicines which have a high dose. Herbal extracts generally have characteristics of sticky, hygroscopic and therefore have poor flowability and compressibility. In

addition, it possesses faintly aromatic odor and somewhat unpleasant taste, so that it took a special method and excipient that could cover these characteristics in order to fulfill with requirements of quality, safety, efficacy and preferred by consumers. FDT using the squash (Luffa acutangula (L) Roxb) fruit extract are disintegrated and dissolve rapidly in saliva is proposed. Excipient used is made by the coprocess maltodextrin succinate (MDS), polyvinylpyrrolidone (PVP) and mannitol (Mnt) ratio of 1: 1: 8; 2: 1: 7 and 3: 1: 6 then characterized.

The mass of FDT was made by three methods are co-process excipient was added the extract and sprayed drying (formulas F1, F2, F3), co-process and sprayed drying of excipient then physically added the extract (formula F4, F5, F6), physically mixed the extract with excipient without co-process (formula F7, F8, F9), then each mass of FDT was compressed then the resulting FDT was characterized and evaluated. The hedonic test and the efficacy test in experimental animals have done and some testings on anti-metabolic syndrome, acute toxicity, phytochemical screening and standardization were also carried out to the active fraction of squash fruit extract.

The results indicated that the FDT F2 formula showed the best pharmaceutical performance and meet the characteristics of pharmacopoeia. In the short-term stability testing, FDT did not appear to physical changes, while in the hedonic testing resulted acceptable palatability. Cucurbitacin compound which was found in the squash fruit extract and in the blood serum of animals treated by FDT was suspected as active substance, pharmacological experiments confirm its therapeutic efficacy and safety. In conclusion, the active fraction of squash fruit had successfully created FDT using a single excipient of MDS-PVP-Mnt (ratio of 2: 1: 7) with co-process - spray drying method and can be an alternative as antimetabolic syndrome.