

Formulasi, uji stabilitas fisik dan uji manfaat shampoo mikroemulsi minyak biji mimba pada ketombe derajat ringan-sedang = Formulation, physical stability test and clinical efficacy test of neem seed oil mcroemulsion shampoo on mild-moderate dandruff

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Abstrak

Ketombe adalah kelainan kulit kepala kronik, ditandai dengan skuamasi dan terkadang rasa gatal. Ketombe dialami oleh hampir 50% populasi pasca-pubertas, mengenai semua etnis dan semua jenis kelamin dan sebagian besar berupa ketombe derajat ringan-sedang. Hingga saat ini, ketombe merupakan masalah kesehatan dan estetika yang menonjol pada masyarakat karena dapat mengganggu kualitas hidup.

Etiopatogenesis ketombe meliputi faktor endogen dan eksogen, di antaranya faktor mikroorganisme (terutama *Malassezia* sp), hiperproliferasi epidermis dan kondisi seboroia. Pengobatan konvensional terhadap ketombe belum memuaskan, sehingga perlu dicari alternatif lain, misalnya shampoo berbahan aktif minyak biji mimba (MBM) yang secara *in vitro* berefek anti-*Malassezia*, anti-inflamasi, antiproliferatif, antihistamin dan imunoregulator. Namun karena MBM bersifat hidrofobik, perlu dihasilkan shampoo MBM dalam bentuk shampoo mikroemulsi yang stabil dan efektif.

Pada penelitian ini, dilakukan formulasi, uji stabilitas fisik dan uji manfaat shampoo mikroemulsi MBM pada ketombe derajat ringan-sedang. Rancangan uji manfaatnya adalah uji klinis acak terkendali buta ganda, memakai metode modifikasi half-head technique dengan DSS (Dandruff Severity Score). Setelah melalui masa persiapan selama 1 minggu, subjek menjalani masa perlakuan selama 2 minggu dengan menerima perlakuan shampoo MBM pada satu sisi kepala dan shampoo plasebo pada sisi kepala lain secara acak. Pada akhir masa persiapan dan perlakuan, diukur DSS dan berat skuama pada tiap sisi kepala. Analisis statistik dilakukan dengan menggunakan uji t berpasangan. Hasil penelitian menunjukkan bahwa formula shampoo mikroemulsi MBM stabil secara fisik selama 12 minggu penyimpanan dan efektif dalam menurunkan derajat keparahan ketombe secara bermakna dibandingkan plasebo ($p < 0,001$).

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Dandruff is a chronic scalp condition characterized by scaling and sometimes itching. Nearly 50% post-pubertal population in all ethnic and gender are dandruff sufferers, majority with mild-moderate dandruff. Nowadays, dandruff is health and aesthetic problem in society because dandruff can degrade quality of life. Ethiopathogenesis of dandruff is influenced by endogen and exogen factors, such as microorganism (especially *Malassezia* sp), epidermal hyperproliferation and seborrhoeic condition. Conventional treatment of dandruff is not yet satisfactory. Thus the search of alternative treatment will still be needed, including shampoo that has neem seed oil (NSO) as an active ingredient, which has *in vitro* anti-*Malassezia*, anti-inflammatory, antiproliferative, antihistamine and immunoregulatory effects. However, due to hydrophobicity nature of NSO, we need to produce a stable and effective NSO microemulsion shampoo.

This research conducted formulation, physical stability test and clinical efficacy test of NSO microemulsion shampoo on mild-moderate dandruff. The design of efficacy test was a double blind randomized controlled

clinical trial by modifying halfhead technique and DSS (Dandruff Severity Score) methods. After run-in period for one week, a subject went through a two-week intervention period by receiving NSO shampoo on one side of the head and placebo shampoo on the other side. At the end of run-in and intervention periods, DSS and weight of squames were measured on each side of the head. Paired t test was used for statistical analysis. The results showed that NSO microemulsion shampoo formula was stable in a twelve-week storage and significantly effective in lowering dandruff severity comparing to placebo ($p < 0,001$).