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STANDARDIZATION AND EVALUATION OF ARTICULIN® FORTE TABLETS

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ABSTRACT
Herbal medicines have a long therapeutic history and are still serving the needy. However, the quality control of herbal medicines still remains a challenge because of the complex nature of the phytoconstituents and therefore it is difficult to establish standards for raw materials and finished products. The objective of the present study is to evaluate Articulin® Forte tablets which is a well-known herbomineral formulation used for rheumatoid arthritis. The tablets were evaluated for physical parameters, fluorescence analysis and identification by TLC analysis.
Keywords: Articulin® Forte, Guggul, Ashwagandha, Haridra, Fluorescence.

INTRODUCTION

"Health for all" is a dream and a goal which humanity at large shares and strives for. Unfortunately, it has now been proven without doubt that modern pharmaceuticals are and will remain out of reach for a large proportion of the human population in the near future. This has created an appreciation and a need for the use of other sources of human knowledge to provide common health benefits. The use of herbs as medicine is the oldest form of healthcare known to mankind and has been used extensively[1]. Although, most of these applications are unorthodox, it is however a known fact that over 80% of the world population depends on herbal medicines and products for healthy living[2]. The World Health Organization (WHO) recognized this fact in the early1970s and encouraged governments to effectively utilize local knowledge of herbal medicines for disease prevention and health promotion. However, herbal medicines suffer from a range of shortcomings. These include insufficient and unacceptable evidences of safety, efficacy, standardization, and inconsistent manufacturing practices[3]. Reproducible efficacy and safety of phytopharmaceuticals is based on reproducible quality. Therefore, if phytopharmaceuticals are required to be regarded as rational drugs, they need to be standardised and pharmaceutical quality must be approved[4, 5]. In pharmacological, toxicological, and clinical studies with herbal drugs, their composition also needs to be well documented in order to obtain reproducible results[6]. The World Health Organization has published guidelines to ensure the reliability and repeatability of research on herbal medicines[7, 8]. A system of standardisation has to be established for every plant medicine in the market because the scope for variation in different batches of medicine is enormous[9]. In the present study, Articulin® Forte tablets were analyzed by various analytical parameters including fluorescence analysis, organoleptic characters and TLC techniques with the intention to evaluate and standardise this well known herbomineral formulation.

MATERIALS AND METHODS

Articulin® Forte Tablets containing Ashwagandha, Guggul, Haridra powder and purified Jasada Bhasma were manufactured in Eisen Pharmaceutical Co Pvt Ltd Pune. Guggul purchased from local market was purified on the basis of Indian Medicinal Systems of Ayurveda [10].

Chemicals: All the solvents and chemicals used were of analytical grade and purchased from Qualigens.

Preparation of granules: All the powders were passed through 50 mesh and granules were prepared by wet granulation method.

Evaluation of moisture contents of granules: Moisture content of the granules was determined by IR balance method.

Preparation of tablets: The tablets were prepared by 16 station tablet punching machine.

Evaluation of tablets

- Proximate analysis, heavy metal testing and microbial testing: The tablets were evaluated for ash value, extractive value, moisture content, heavy metal analysis and microbial analysis.
- Fluorescence analysis of tablets: Chemical reagents were determined under ordinary and ultraviolet light [11]. 1 mg of the sample was taken in a glass slide and treated with various reagents for the presence of their fluorescence characters under ultra-violet lamp.
- Organoleptic characters of tablets: Organoleptic evaluation refers to evaluation of the formulation by colour, odour, taste, texture etc[12].

Physical parameters: The tablets were evaluated for average weight, Length, thickness, width, hardness, disintegration time.

Identification of individual component: Guggul, Ashwagandha and Haridra were identified by TLC methods[13]. Following TLC systems were used for identification

Guggul- Light petroleum: ethyl acetate (3:1)
Ashwagandha- Chloroform: Methanol (9:1)
Haridra- Chloroform: Ethanol: Glacial acetic acid (94:5:1)

Identification of Guggul by UV method: 0.005% w/v ethanol solution was examined under UV in the range 230 nm to 360 nm.

Table 1: Moisture content of granules of Articulin® Forte tablets

Parameter	Limit	Results
Moisture contents of granules (By IR balance method)	2-3.5%	3.2%

Table 2: Fluorescence analysis of Articlin® Forte tablets

S No	Treatment with chemical reagents	Visible/day light	UV light at 254nm
1.	Powder as such	Yellowish green	Yellow
2.	Powder + 1N Sodium hydroxide in water	Brown	Bright yellow
3.	Powder + 50% Hydrochloric acid	Yellow	Bright yellow
4.	Powder + 50% Sulphuric acid	Yellow	Bright yellow
5.	Powder + 50% Nitric acid	Brown	Greenish yellow
6.	Powder + Petroleum ether	Yellowish brown	Yellow
7.	Powder + Chloroform	Yellowish brown	Yellowish green
8.	Powder + Picric acid	Yellowish brown	Bright yellowish green
9.	Powder + 5% Ferric chloride solution	Dark brown	Black
10.	Powder + 5% Iodine solution	Black	Black
11.	Powder + Methanol	Yellow	Pale yellow
12.	Powder + (Nitric acid + Ammonia)	Orange	Yellow

Table 3: Organoleptic parameters of Articulin® Forte tablets

Parameter	Observation
Colour	Yellowish brown
Taste	slightly bitter
Odour	Characteristic
Appearance	smooth coated

Table 4: Physical parameters of Articlin® Forte tablets

Parameter	Limit	Results
Average weight	1.163 gm	1.1569 gm
Length	19.1±0.2 mm	19.24 mm
Thickness	6.6±0.2 mm	6.58 mm
Width	8.0±0.2 mm	8.12 mm
Hardness	NLT 6.0 kg	10.40 kg/cm^2
Disintegration time	NMT 60 min	18 min 10 sec

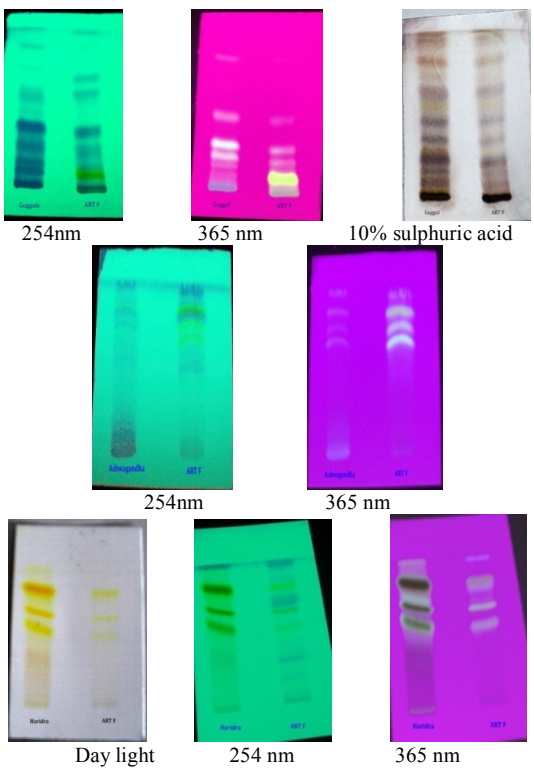

Figure 1: Identification of Guggul, Ashwagandha and Haridra by TLC method

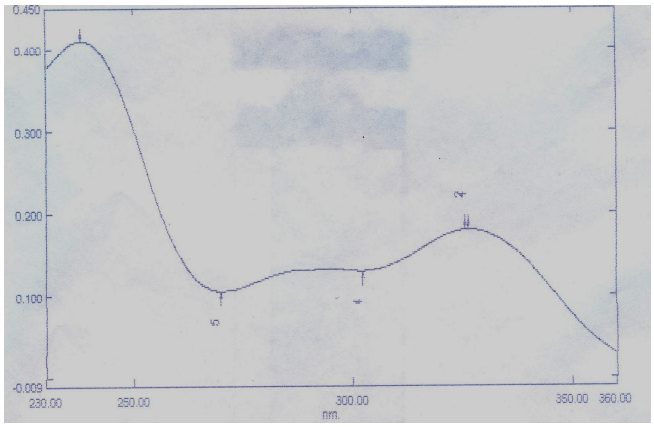

Figure 2: Identification of Guggul by UV

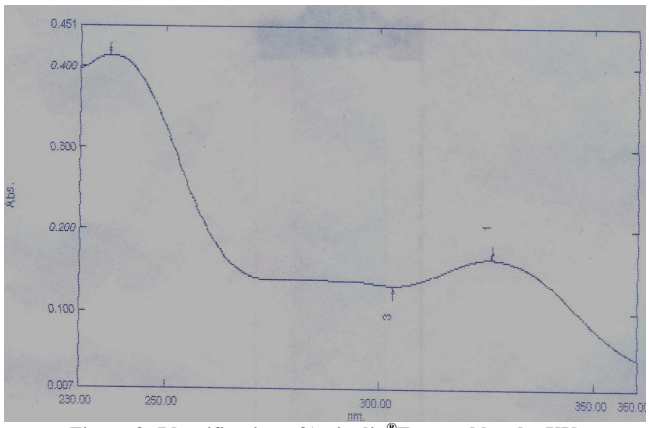

Figure 3: Identification ofArticulin® Forte tablets by UV

RESULTS AND DISCUSSION

Articulin® Forte is a herbomineral formulation widely used for arthritis. Tablets were manufactured using wet granulation method. All the powders were passed through 50 mesh. Guggul purified as per Ayurvedic text[14] was used as binder in the formulation. Granules so formed were passed through multi-mill 6mm screen. These granules were dried in Fluidized Bed Dryer and again passed through 18 mesh. Moisture content of granules is one of the important parameter in tablet manufacturing. It was found that the moisture content of the granules was in the specified limits (Table 1).The granules were compressed by tablet punching machine. The tablets were subjected to various analytical techniques. Evaluation of Articulin® Forte tablets for the parameters viz proximate analysis, heavy metal testing and microbial testing have already been published in our previous paper[15]. Fluorescence is an important phenomenon exhibited by various chemical constituents present in plant material[16]. If the substances themselves are not fluorescent, they may often be converted into fluorescent derivatives by reagents hence some crude drugs are often assessed qualitatively in this way and it is an important parameter of pharmacognostic evaluation[17]. The results are presented in table 2. Articulin® Forte tablets were studied for organoleptic characteristics like colour, odour, taste and appearance (Table 3). Organoleptic characters are the basic criteria for identification. It is based on nature of the raw material. Articulin® Forte tablets were studied for post compression parameters which included average weight, hardness, friability, length, width and thickness (Table 4). The results were found satisfactory and reproducible. Identification of formulation and each of its components by TLC is an important part in standardization and evaluation. Co- TLC was performed for each component and Articulin® Forte tablets using reported solvent systems. A specific identification test for Guggul is mentioned. The co- TLC of Guggul showed presence of six spots at R_f 0.19, 0.29, 0.39, 0.51, 0.71 and 0.89. The co- TLC of Ashwagandha showed presence of three spots at R_f 0.88, 0.71 and 0.83. The co- TLC of Haridra showed presence of three spots at R_f0.72, 0.81, 0.90(Figure 1). When ethanolic solution of Guggul and Articulin® Forte tablets were studied for UV analysis, the absorption maxima was found at 238 nm, 326 nm and 237 nm, 325 nm respectively (Figure 2 and 3).

CONCLUSION

The study reveals that sufficient quality control parameters were followed during the manufacturing process. Organoleptic characteristics, moisture content, fluorescence analysis, physical parameters, TLC analysis indicates genuineness of finished product.

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