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Formulation and Evaluation of Secnidazole Film Coated Tablets

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Abstract:
Film coated tablets are designed to rupture and expose core tablet at the desired location in the gastro intestinal track the coating is done by using film coating solutions which are polymers in nature, forming smooth coat over core tablet. The present study it was aimed to formulate film coated tablets of secnidazole by wet granulation and the granules are compressed for tablets and they are coated with polymers for getting film coated tablets at specified conditions and the evaluation of film coated tablets for the following parameters as description, average weight, weight variation, hardness test, thickness, dissolution, related substances, disintegration time and assay of tablet for compliance with acceptance criteria, for formulation of secnidazole film coated tablets.
Key words: *Film coated tablets, Secnidazole, Formulation.*

INTRODUCTION

Secnidazole is 1-[2-Hdroxy]-2-methyl-5-nitroimidazole, used as antiprotozoal and antiamoebic [1]. It is a derivative of 5-Nitroimidazoles closely related to metronidazole [2]. Film coated tablets are compressed tablets coated with a thin layer of a polymer capable of forming a skin like film [3-5]. The film is usually colored and has the advantage over sugar coating in that it is more durable, less bulky and less time consuming to apply. Film coating solutions may be non aqueous or aqueous. The non aqueous solutions Contains the following types of material to provide the desired coating to the tablets a film former capable of producing smooth [6-8], thin films reproducible under Conventional coating conditions and applicable to a variety of tablets shapes Example is as cellulose acetate phthalate. Allowing substance provides water solubility or permeability to the film to ensure penetration by body fluids and therapeutic availability of the drug. Example is polyethylene glycol. A plasticizer to produce flexibility and elasticity of the coating and durability is provided by castor oil. A surfactant is used to enhance spread ability for the film during application [9-11], example is polyoxyethylene sorbitan derivatives. Present study shows the formulation of film coated tablets and their evaluation for compliance to acceptance criteria.

MATERIALS AND METHODS

The drug secnidazole was supplied by Unichem Laboratories Ltd., other chemicals like Magnesium Stearate, Mciro cystalline cellulose, Gelatin, Starch, Sodium Starch Glucollate, Collodial Anhydrous Silica, Titanium dioxide, Hydroxy Propyl methyl Cellulose, Macro Gel, Industrial Methylated Spirit and Dichloro Methane used were AR grade.

The formulation was prepared so as to each film coated tablet should contain 1 g of secnidazole. Area was rapt clean and dry and free from microbial contamination. All the ingredients such as secnidazole, Lactose and HPMC k 100 were sifted through 40#. The Sifted mixture was mixed thoroughly for 15 minutes. Polyvinyl pyrrolidine binding solution (PVP) was soaked in isopropyl Alcohol and methylene chloride in a stainless steel vessel. It was dissolved under Constant stirring. Binder solution was poured slowly to the above mixture and mixed for two to three minutes at high speed until coherent mass was achieved. The Wet Coherent mass was passed through 30# and collected in a clean labeled container. The Wet Granules wear loaded into tray drier and dried at 50^{o}C till it was dried. Size Reduction for dried granules is by sifting through 16# sieve. The sifted granules were collected in a clean labeled container.The dried granules were loaded into a blender. Magnesium stearate was added into it mix

for 15 minutes and stored in a double polybag. The above granules were compressed with the help of compression machine (Cod press part-45)12/32 punch size at 30 RPM. After compression, weight variation, Thinness, hardness, friability, disintegration time and dissolution test were measured.

Preparation of coating solution:

HPMC K 100, Isopropyl alcohol, methylene chloride, and titanium dioxide were mixed together to get a coating solution. The uncoated, de-dusted tablets were loaded into the coating pan and the tablets were warmed up to 50^{o}C. The Coating solution was sprayed over the warmed tablets using 1.5mm air nozzle spray gun for efficient coating. Hot air was passed between each application of coats. Tablets bed temperature during coating procedure should not exceed 35^{o}C, coating parameters specification is shown in Table 1.

Table 1: Coating parameter Specification

Specification	***Film Coated***
Coating pan	12”
Pan speed	6 RPM
Atomizing air prenure	3 to 4kg/cm^2
Intent air temperature	45 to 50^{0}C
Outlet air temperature	40 to 45^{0}C
Bed temperature	30 to 35^{0}C
Predrying in pan	15 min at 45^{0}C
Final drying in pan	1-2Hrs at 45^{0}C
Post draying in pan	1Hr air drying
Relative humidity	40 ± 5%

Evaluation of Film coat tablets:

White, capsule shaped, film coated with score mark on one side. 20 tablets were selected at random and average weight was calculated, which should not more than two of the individual weights deviated from the overage weight by ±5% and none deviated by more than ±10% of average weight.

The retention time of major peak due to secnidazole in chromatogram of the sample preparation correspond to that of the standard preparation as obtained in assay. Disintegration test on six tablets was performed by suspending the assembly in the beaker containing water where the temperature was maintained between 36^{o}C and 38^{o}C for NMT 30 min. Dissolution test was performed by using USP, Type 11 (Paddle).

Standard preparation:

50 mg of secnidazole working standard was weighed accurately in a 50 ml volumetric flask, dissolved and diluted to 50ml with dissolution medium. 2 ml of the above solution was taken in a 100ml volumetric flask and diluted up to the mark with dissolution medium.

Sample preparation:

One tablet in each of the dissolution jars containing 900ml of dissolution medium and dissolution is performed at the end of 30 minutes, supplicant amount of medium withdrawn and filtered through 0.454 µm membrane filter. In 100ml volumetric flask 2ml of filtrate is diluted up to the mark with dissolution medium.

System suitability:

Six readings of standard preparation were taken the relative standard deviation of 6 replicate reading is calculated which is NMT 2.0%.

Absorbance was measured for the standard and the sample preparation at 294mm on a spectrophotometer using dissolution medium as blank. The percentage of secnidazole release was calculated by using

% of secnidazole release = (ATxWSx18xP)/(AS x LC)

Where,

AT = Absorbance of sample preparation

AS = Absorbance of standard preparation

WS = Weight of working standard in mg.

P = Potency of secnidazole working standard in % on as in basis.

LC = Label Claim in mg/tablet.

Preparation of reference Solution:
50mg of secnidazole working standard was weighed accurately in a 100ml volumetric flask. 80ml mobile phase was added and sonicated. The volume was diluted up to mark with mobile phase; 5ml of the above solution was transferred in 100 ml volumetric flask, diluted with mobile phase. Further 1 ml of dissolution was diluted to 10 ml with mobile phase.
Sample preparation:
10 tablets were weighed and powdered. From the powder equivalent to 50 mg of secnidazole was weighed and transferred in a 100 ml volumetric flask. About 80ml of mobile phase was added and sonicated for 5 minutes. The volume was made up to the mark with mobile phase. The above solution was filtered through 0.45 μm membrane filter.
System suitability:
Six replicate injections was made of reference solution into the chromatograph as per the conditions prescribed and recorded the responses for the same. The relative standard deviation for replicate injections is NMT 5.0%. Separately 20ul of the mobile phase reference solution (six) and sample solution injected into the chromatograph and recorded the response for the same.

RESULTS AND DISCUSSION

Film coated tablet are punched by using PVP as binding agent, and the tablets are evaluated for average weight as 1279 mg, weight variation as 1250.10 to 1290.60mg, Hardness Test as 5kg/cm^2, Thickness as 7.11 mm, dissolution as 97.87%, Related substances as individual impurities, a) 0.082%, b) 0.052% and the total impurities 0.137%, disintegration time as 18 min, assay as 98.34% of label claim and % relative standard deviation is 0.2%. All the above evaluation values comply with acceptance criteria shown at table 2.

Table 2: Evaluation of Film coated tablet

Specification	***Observation***	***Acceptance Criteria***	***Inference***
Description	White capsule shaped, Tablets with Score mark on one side	White capsule shaped tablets with score mark on one side.	Complies
Average Weight	1279 mg	1275 + 4.0%(1273 to 1279)	Complies
Weight variation	1250.10 to 1290.60mg	± 5% of Avg wt. (1275 to 1284 mg)	Complies
Hardness Test	5kg/cm^2	NLT 3 kg/cm^2	Complies
Thickness	7.11 mm	7.25 ± 7mm	Complies
Dissolution	97.87%	NLT 80% of label claim	Complies
Related substances	1. Individual impurities a.)0.082% b.)0.052% 2. Total Impurities -0.137%	1. Individual impurities NMT 1.0% 2. Total impurities NMT 2.0%	Complies
Disintegration time	18 min	NMT 30 min	Complies
Assay	98.34% of label claim % RSD = 0.2 %	95.00 to 110.00%of label claim % RSD should be less than 2%	Complies Complies

CONCLUSION

A relatively simple secnidazole film coated tablets formulated and evaluation parameters such as average weight, weight variation, hardness test, thickness, dissolution, disintegration time and assay complies within the limit. It shows high mechanical strength and low friability. The film coating showed a little effect of disintegration and dissolution of the cores.

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