SHORT COMMUNICATION

DISSOLUTION TEST FOR OMEPRAZOLE PELLETS 8.5% (HIGH DISSOLUTION): OPTIMIZATION AND STATISTICAL ANALYSIS.

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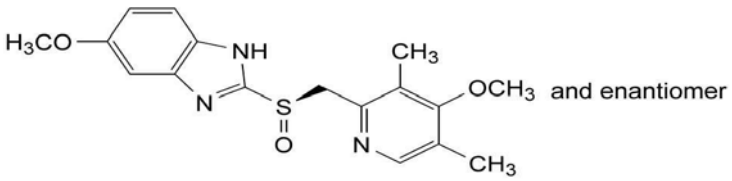
ABSTRACT

A comparison of Innovator sample of omeprazole dissolution test used by USP 30 method, evaluated, and discussed. Dissolution medium (0.1N hydrochloric acid & Phosphate buffer pH 6.8), apparatus (paddles) and time (2hours and 0,5,10, 20,30,45 and 60min) were analyzed. The determination was accomplished by spectrophotometry at 305 nm. Analysis of variance (ANOVA) with six repetitions, with multiple comparisons between means conducted by USP30 method .USP limits dissolution Not less than 75% after 30 minutes, where as our In-House Limit Not less than 85% after 10 minutes . After the comparative analysis of the results, optimal dissolution conditions were determined as follows: buffer as dissolution medium, paddles at the stirring speed of 100 rpm as apparatus and time of 0,5,10, 20,30,45 and 60min. The method was applied to the dissolution test of samples from three batches of innovator, produced by two different laboratories. Comparative to innovator sample it will give better dissolution.

Keywords: *Omeprazole, High Dissolution, USP30 method.*

INTRODUCTION

Omeprazole is used for the Treatment of peptic ulcer. Chemically Omeprazole is known as 5-methoxy-2-[(*RS*)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]-sulphinyl]-1*H*-benzimidazole.
It is reported in USP, BP, of the pharmacopoeias. A survey of literature reveals that UVmethods[1,2,3] are reported for the determination of Formulation and in vivo evaluation of omeprazole buccal adhesive tablet, Bioequivalence evaluation of two omeprazole enteric-coated formulations in humans, and Pharmacokinetic comparison of Omeprazole Capsules and a Simplified Omeprazole Suspension.



Omeprazole

(5-methoxy-2-[(*RS*)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]-sulphinyl]-1*H*- benzimidazole)

Process Innovator used ingredient : Omeprazole 10mg, Lactose 70.0mg, Mannitol 20.0mg, Hydroxy propyl cellulose 0.5mg, Disodium Hydrogen phosphate 0.5mg, Sodium Lauryl sulfate 0.5mg,and Talc 0.5mg. Total 102.0Mg.

Process used Ingredient: Omeprazole 10mg, **Cross linked poly vinyl pyrrolidone 2.1Mg**, Lactose 67.9mg, Mannitol 20.0mg Hydroxy propyl cellulose 0.5mg, Disodium Hydrogen phosphate 0.5mg, Sodium Lauryl sulfate 0.5mg, and Talc 0.5mg. Total 102.0Mg.

Cross linked poly vinyl pyrrolidone applications and benefits:

Absorbs water and gases. Also complexes with toxins.Used in some countries to treat gastrointestinal disorders and as a anti-diarrhea agent in human and also in veterinary applications.

Drug release:

Apparatus 2; 100 rpm

Medium 1 : pH 6.8 phosphate buffer 900ml

Time: 45 minutes

Determine the amount of $C_{17}H_{19}N_3O_3S$ dissolved, using the following method

Medium preparation :

Dissolve 6.80g of potassium hydrogen ortho phosphate in 1000 ml water maintain the pH to 6.8±0.05.

Standard preparation:

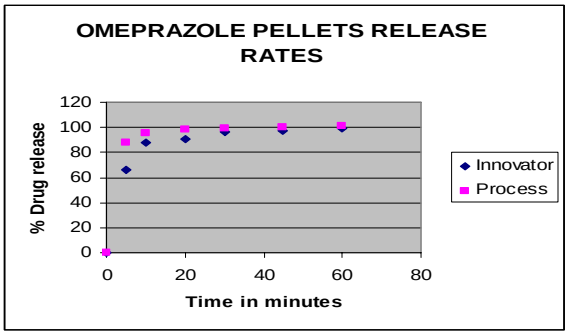
Transfer about 50mg of omeprazole WS, accurately weighed, to a 250 ml volumetric flask to that add 50ml of alcohol, subjected to sonication for 10 minutes and dilute with the sodium borate solution (0.01M) to the volume. Throughly Mix and filter. Transfer 5.0ml of this solution to a 100 ml volumetric flask, dilute with medium to the volume and mix.

Procedure :

Determine the amount of $C_{17}H_{19}N_3O_3S$ dissolved, by employing UV absorption at the wavelength of maximum absorbance at about 305 nm on filtered portions of the solution under test, suitably diluted with dissolution medium, if necessary, in comparison with a standard solution having known concentration of omeprazole in the same medium.

Release Rates Innovator and process:

Time in Minutes	Innovator	process
0	0	0
5	66.19	88.3
10	88.26	95.8
20	91.15	98.7
30	96.76	99.3
45	97.74	99.9
60	98.94	101.2



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