

## Promethazine: Travel Friendly Dosage Form

Shazia Hassan, Bhanu S Kumar, Robin Kumar, Shivam Rai

*Student, JBIT college of pharmacy, Dehradun, Uttarakhand*

*Student, Uttarakhand technical university, Dehradun, Uttarakhand*

Submitted: 20-09-2022

Accepted: 30-09-2022

### ABSTRACT:

The purpose of this article is to create awareness about Promethazine chewable tablets and formulate it in order to suspend it for frequent use in case of emergency as an antiemetic to prevent nausea and vomiting. Promethazine tablet is comprised with granules taste bitter and is masked in order to make it palatable. Promethazine tablet is needed to be administered before 1 hour or so in order to show its effectiveness at the time of need. Tablets that are formulated were taken for evaluation of tensile strength, drug content uniformity, disintegration time, drug polymer interaction, drug interaction and friability. The main purpose is to make this dosage form palatable and available for even the patient who cannot administer oral tablet dosage form that are of old age and for children as well.

### KEYWORDS:

Promethazine hydrochloride, chewable tablet, oral administration, taste masking.

### I. INTRODUCTION:

One important drawback of tablets is to make it palatable and administer it through oral route by pediatrics, geriatrics or traveling patients. If the latter do not have access to water chewable tablet were considered to be the most desirable if recommended for Dysphasia patient who shows general difficulties in swallowing of tablets.

Promethazine hydrochloride is a H1 receptor antagonist and act as prophylactic or hypersensitivity against motion sickness. The major drawbacks of promethazine hydrochloride is

to cover or mask the bitter taste of granules used to formulate the tablet by using different techniques. Chewable tablets are required to be broken and masticated within buccal cavity in order to provide medication immediately or after 2-3 minutes whenever needed or required. Chewable tablets are not only friendly to human but also are effective for veterinary use. They provide a convenient means of drug delivery.

### II. FORMULATION:

Chewable tablet can be prepared in various shapes, flavors and colors. Chewability of a tablet is defined as the ease or difficulty in breaking of a tablet by chewing. There are variety of mechanical parameters that effects the chewability of tablet. Not only mechanical parameters but biological and physicochemical parameters also impact the chewability the factors that should be monitored includes grittiness which is influenced by particle size with smaller particles low grittiness which is much more acceptable. There are some factors that are undesirable which includes excessive gumminess, or viscosity, chalkiness and teeth stickiness.

Tests include indirect access to chewability like hardness test (tablet breaking force), tensile strength and chewing difficulty index and various other test which are conducted by mild exposure to human saliva as because of tablets route of administration and absorption will be the buccal cavity.

TABLE 1. FDA CHEWABLE TABLETS GUIDANCES.

Attribute	Recommendations
Tablet Hardness	Less than 12 kp; higher hardness values may be considered if justified(e.g., tablet rapidly softens or disintegrates after brief (<30 seconds) exposure to stimulated saliva)
Disintegration	Typically the same specifications as immediate-release tablets; important to determine since some individuals may swallow tablets without chewing.

Dissolution	<ul style="list-style-type: none"> <li>•Typically the same specifications as immediate-release tablets. Does not apply to chewable modified-release products</li> <li>• In vitro dissolution testing should be conducted on intact chewable tablets since some individuals may swallow tablets without chewing</li> </ul>
Others	<ul style="list-style-type: none"> <li>•Specific to the individual product (e.g.. tablets with functionally coated particles should not be adversely affected by chewing)</li> <li>•Tablet size, shape, thickness, friability, palatability.</li> <li>• The chewing difficulty index is discussed in the guidance; however limits are not provided</li> </ul>

**Table 2. PROPERTIES OF COMMON BULK AND HIGH INTENSITY SWEETENERS.**

Sweetener	Relative sweetness (compared to sucrose)	Heat of solution (J/g) (all values are endothermic)
Sucrose	1.0	18
Dextrates	0.5	105
Fructose	1.2_1.7	50.2
Glucose (dextrose)	0.65	60.6 (anhydrous) 105(monohydrate)
Lactose	0.2 ( $\alpha$ -lactose) 0.4( $\beta$ -lactose)	56.2 ( $\alpha$ -lactose monohydrate)
Isomalt	0.45 – 0.65	39.3
Mannitol	0.7	120.9
Sorbitol	0.6	110.9
Xylitol	1.0	157.1

**HIGH INTENSITY OR BULK SWEETENERS**

Acesulfame potassium	200
Aspartame	180
Glycyrrhizin	50 – 100
Saccharin sodium	300
Stevia (steviol glycosides)	300
Sucralose	600

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