Introduction

This document provides guidance for NDAs and ANDAs having tablets that have been scored. It provides:

■ **Guidelines to follow,** data to provide, and criteria to meet and detail in an application to support approval of a scored tablet.

■ **Nomenclature and labeling** for approved scored tablets

This guidance does not address specific finished product release testing, where additional requirements may apply to scored tablets.

Source: https://www.slideshare.net/nagaajaykumardintakurthi/guidance-on-tablet-scoring

What is a Score

A score is a useful feature for the patient who, for instance, wants to switch from a name-brand to generic product and may need to halve tablets to maintain a consistent dosage regimen. By some accounts, this is happening more often, as insurance companies and doctors are increasingly recommending that patients split tablets for proper dosing or sometimes as a cost saving measure.

Scoring has also been an issue in determining whether a generic drug is equivalent to its reference product. Whether or not a tablet is scored (and scored properly) can play a role in the cat-and-mouse game that originating manufacturers play with would-be generic competition. A reference drug may have a well-defined score while a generic product may only have a cosmetic breakline—in such a case, is the generic truly equivalent?

Why Score

Scoring of tablets facilitates the splitting of tablet into fractions when less than a full tablet is desired for a dose. (For adjusting the dose in the same manner as the RLD) Although there are no standards or regulatory requirements that specifically address scoring of tablets, Agency recognizes the need for consistency scoring between a generic product and its RLD. Agency concluded that tablet splitting have safety issues in some cases. Concerns with splitting of tablet include variations in the tablet content, weight, dissolution or disintegration. In addition, there may be stability issues with splitting tablets. How much drug is present in split tablet and available for absorption.

As an outgrowth of these discussion,Agency is providing recommendations for applicant content regarding the scientific basis for functional scoring on solid oral dosage form products to ensure the quality of both NDA andANDA scored tablet products. è Guidelines and Criteria è Nomenclature and Product labeling

Pill Splitting

Guidelines and Criteria

The draft guidance's fundamental guidelines and criteria are:

1. The dosage amount meant to be achieved after splitting the tablet should not be below the minimum therapeutic dose indicated on the approved labeling.
2. The scored dosage form should be safe to handle and not pose risk of unintended drug exposure.
3. Modified release products for which the control of drug release can be compromised by tablet splitting should not have a scoring feature.
4. The split tablet, when stored in standard high-density polyethylene pharmacy bottles and caps (no seal), should meet established stability requirements for a period of 90 days at 25º C, plus or minus 2º C/60 percent Relative Humidity (RH), plus or minus 5 percent RH.
5. The split tablet portions should meet the same finished-product testing requirements as for a whole-tablet product with equivalent strength. A risk assessment should be provided to justify the tests and criteria for product with the proposed functional score.
6. The scored tablet should be tested using the indicated patient population to ensure patients can split the tablet correctly, as labeled.
7. The scoring configuration of generic drug products should be the same as the reference drug.
8. New study data on tablet splitability should be provided during postapproval for any product changes per FDA's SUPAC guidances.

Nomenclature

New products that meet the above-referenced criteria can be labeled as having functional scoring. Such labeling should appear in all of the following sections of the prescribing information:

- "Dosage Forms and Strength" section of the Highlights.
- "Dosage Forms and Strength" section of the Full Prescribing Info.
- "How Supplied" section of the Full Prescribing Information.