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Pharmaceutical Solid Oral Dosage Form Analysis: Literature Review

Yesuneh Tefera Mekasha*

Veterinary pharmacy department, College of veterinary medicine, University of Gondar, Ethiopia

*Corresponding author: Yesuneh Tefera Mekasha, Veterinary pharmacy department, college of veterinary medicine, University of Gondar, Addis Ababa, Ethiopia

Abstract

Dosage form is defined as a physical form of a drug such as; a solid, liquid or gas by which it is delivered in it's a proper form to particular sites of action within the body. The pharmaceutical analysis of finished solid oral dosage forms is presented here from the aspect of what makes the delivery form unique and successful, i.e., the physical properties and the state of the drug substance in the matrix. During product development, many analytical techniques can be brought to bear that provide a characterization of the product and guide the pathway to the optimum formula. In many cases, analytical techniques can be used to assess the effects of processing parameters and provide a means to predict the performance and stability of the final product. Techniques that apply to in situ analysis of the dosage form, its precursor granulations, or powders are discussed. Applications of solid state NMR, FTIR microspectroscopy, visual and scanning electron microscopy, Raman spectroscopy, NIR analysis, thermal techniques, mass spectrometry, and imaging techniques are presented. A summary of new high throughput applications of methodologies is also presented. Examples are fiber optic dissolution technology, flow injection analysis, NIR analysis, and robotics. These techniques provide data with less analyst involvement and allow a more thorough batch quality assessment. Therefore; this review paper give a precise information regarding quality assessment of pharmaceuticals solid dosage forms through application of analytical techniques across the world because they have health impact.

Keywords: Pharmaceutical Solid dosage form, Analytical techniques, Drug substances, Drug product

Abbreviations: API: Active Pharmaceutical Ingredients; DTA: Differential Thermal Analysis; FTIR: Fourier Transform Infrared Radiation; HPLC: High Performance Liquid Chromatography; HPMC: Hidroxy Propyl Methyl Cellulose; ICH: International Conferences on Harmonization; IVIVC: In-Vitro-Invivo correlation; NIR: Near Infrared Radiation; SUPAC: Scale-up and Post-Approval Change

Introduction

Pharmaceutical solid dosage forms for oral use are the most common pharmaceutical formulation types worldwide. They are complex multicomponent system that may be available in many diverse structures such as powders, granule, compressed tablet, chewable tablet and capsules [1]. Solid oral dosage forms were the first dosage forms to be considered for worldwide regulation by the International Conference on Harmonization (ICH). The ICH is a collaborative effort by both industry and regulatory bodies of the United States, the European Union, and Japan [2-4].

Preliminary physicochemical assessment of drug products has a paramount importance in ensuring the quality of drug products. Generic drug products must satisfy the same standards of quality, efficacy and safety as those applicable to the innovator products. In vitro dissolution testing can be a valuable predictor of the in vivo bioavailability and bioequivalence of oral solid dosage forms [5]. When it is incorporated into polymers that are used to modify its physical state or control its release in the gastrointestinal tract. These formulations often present considerable challenges to the pharmaceutical chemist. Solid oral dosage forms are designed to deliver the drug through physiological mechanisms that preside throughout the gastrointestinal tract [6].

The problem of quality assessment of pharmaceutical solid dosage form is important all over the world [7]. Ensuring the quality of medicine is becoming more important and challenging. This generates the need for more fast and smart technique to fulfil the requirement. Pharmaceutical analysis deals with analysis of drugs, pharmaceutical

substances and raw material. It is devoted to stability testing, comparing related substances, determination of impurities. There are various techniques are available for analysis of pharmaceutical solid dosage forms. Noninvasive technique is nothing but the nondestructive method, in that the samples do not touched by the device. Invasive technique can touch the sample and added some solvents, chemicals to determine the quality of sample and analyze that sample [8].

Different techniques are utilized for the analysis of the solid oral dosage form. The one which is used in the modern times are including; Microscopy, X ray Powder Diffractions, Thermal Analysis, Fourier Transform Infrared (FTIR), Micro spectroscopy, Nuclear Magnetic Resonance (NMR) Imaging, Near Infrared (NIR) Analysis, and Raman Spectroscopy [9]. Therefore, the present review was carried out to determine and discuss about analytical separation techniques, tests and specification, physico chemical characterization techniques and quality related regulatory and ICH influences, automation and future direction of Chemometrics and expert" system that will play a major role in the treatment and interpretation of the data; regarding solid oral dosage forms.

General Description of Solid Dosage form Analysis

Solid oral dosage forms provide a highly reproducible and convenient form of drug delivery. Generally easy to manufacture and stable, they are the most common form of self-medication. Immediate controlled and extended release solid oral dosage forms are easy to manufacture, reproducibly and provide convenient delivery systems for self-administered medications. To design effective delivery systems, it is important to understand the behavior and characteristics of the active pharmaceutical ingredient (API) when it is incorporated into polymers that are used to modify its physical state or control its release in the gastrointestinal tract. These formulations often present considerable challenges to the pharmaceutical chemist [10-15]. To design an effective delivery system, it is important to know the physical state of the API in the dosage form; therefore, this chapter will focus to a large extent on the solid state aspects of the solid oral dosage forms. Tests that demonstrate that the state of the API within the dosage unit is in a specified, physical form increase the dependability and understanding of product performance [10-15].

Separation Techniques

Techniques that involve crushing, dissolving, or extracting the API from the dosage form often destroy much of the critical information about the physical characteristics of the sample. Therefore, they are unlikely to provide much information about physical or performance related attributes of the dosage form. Because preparation of a sample for chromatographic analysis involves the use of destructive sample preparation techniques, chromatographic methods will not be discussed in this review, even though high performance liquid chromatography (HPLC) is a dominant technique that has been routinely used during the last 20 years for assay and impurity determinations. Several worthwhile HPLC treatises are readily available [10-15].

Though intriguing and promising new chromatographic techniques such as capillary electrophoresis, capillary electrochromatography, and micellar electrokinetic chromatography continue to be developed, applications for finished solid oral dosage-form analysis are just beginning to appear [16,17]. The use of capillary techniques has increased because of the need for chromatographic alternatives to HPLC. Capillary electrophoresis and related techniques are capable of high separation efficiencies, but they are often limited by injection imprecision, viscosity effects, electro osmotic flow, and sample capacity. An excellent review of these techniques with applications to dosage-form analyses was recently published [18].

Quality-Related Regulatory and ICH Influences

Solid oral dosage forms were the first dosage forms to be considered for worldwide regulation by the International Conference on Harmonization (ICH). The ICH is a collaborative effort by both industry and regulatory bodies of the United States, the European Union, and Japan, in whose proceedings and deliberations this author was privileged to play a role [19-21]. The ICH Quality Section concentrated its efforts on the development of guidelines for method validation and stability studies and specifications for impurities and residual solvents. These guidelines are excellent sources of information regarding the development of and requirements for analytical methodology and validation. In addition, the ICH proposed guidelines for the development of specifications related to drug substance and drug product performance (ICH Q6A and decision trees) [22].

Tests and Specifications

As the modern analytical laboratory evolved, the predominant emphasis was on measurements that demonstrated the purity, identity, and potency of the dosage form. In the latter half of the twentieth century, tests and specifications that measure parameters such as hardness, disintegration, and dissolution were added as an

attempt to ensure consistent product performance [23]. Recently, ICH guidance Q6A has simplified the development of specifications in several ways, not the least of which is the clarification that impurities if already controlled in the API do not have to be controlled in the dosage form unless they are also degradants. For the release assay, this paves the way for simpler, but no less sophisticated methods that require minimal sample preparation. Thus, the future may bring a return to spectroscopic techniques such as ultraviolet/visible (UV/vis) spectroscopy. There also may be increased use of other high-speed and high-precision techniques such as flow injection analysis (FIA) and near infrared (NIR) analysis [24].

The tests for assay, blend uniformity, and content uniformity usually represent a high laboratory resource burden during development and product release. They provide some information on batch execution, but little relevant information regarding its potential performance. These tests are often implemented with an assessment of 30 tablets or less, which might represent an entire production run of 100,000 tablets or more. In an overwhelming number of cases, the assay and content uniformity tests are based upon HPLC. For stability indicating methods, chromatography (also usually HPLC) is required because of the need to monitor or separate possible degradants. HPLC is also the release method of choice for the analysis of drug mixtures. HPLC exhibits good linearity, specificity, and precision, but it is slow and sequential and carries with it high data storage and system suitability requirements [24].

The quantitation of degradation products is critical for ensuring quality. Occasionally, degradants can be toxic, and their presence may indicate a production process that is out of control, poor or inappropriate packaging materials, or improper storage. Methods for the determination of degradation products should be capable of detecting degradants that already have been observed and have the built in capability to detect possible new degradants should they occur. HPLC has become the method of choice for the quantitationof degradants and is frequently combined with the assay test. Conventional HPLC usually demonstrates adequate resolution in the separation of drug substances and their homologues [24].

Physicochemical Characterization Techniques

The ability of a chemical compound to elicit a pharmacological/therapeutic effect is related to the influence of various physical and chemical (physicochemical) properties of the chemical substance on the bio molecule that it interacts.

a. Investigation of physical and chemical properties of a drug substance – alone and or when combined with excipients is crucial during pre-formulation studies.

b. The development of any dosage form new drug, it is essential that certain fundamental physical and chemical properties of drug powder are determined.

c. c. This information may dictate many of subsequent event and approaches in formulation development

d. The physicochemical properties are the first step in the rational development of a dosage form of a drug substance alone and when combined with excipients [25].

Physicochemical characterization techniques are beginning to play a major role in the drug development process because they help us to understand the mechanism of drug delivery. Demonstration of this understanding is expected by the regulatory agencies and is usually an important component of the pharmaceutical development report. Dissolution is the first step in drug delivery by solid oral dosage forms, but the determination of in vitro release profiles provides little, if any, understanding of the mechanism of the release of API from the product matrix [26]. An assessment of the internal structure of the dosage form and the microhomogeneity and morphology of the API in the dosage form can be made with the techniques that are discussed in this review. These techniques include microscopy and energy dispersive X ray spectroscopy, X ray powder diffraction, thermal analysis, FTIR microspectroscopy, NMR imaging, mass spectrometry, and Raman spectroscopy. The collection and interpretation of the results obtained from these techniques can be used to optimize formulation development and ensure the consistency, quality, and stability of solid dosage forms [27].

Microscopy: Light microscopy, PLM, SEM, and transmission microscopy are nondestructive techniques that can provide insight into the composition and homogeneity of the API throughout the dosage for these techniques lead to understanding and a prediction of the dosage form's performance characteristics, such as the dissolution profile, ruggedness of the product. PLM and energy dispersive X ray spectroscopy (used in conjunction with SEM) were utilized to determine how an API is distributed within a granulation. A polarized light micrograph of a cross section of the granulation matrix. Crystals of the intact API are plainly visible within the matrix.

Because the API is a hydrochloride salt, energy-dispersive X-ray spectroscopy, an elemental analysis technique, was

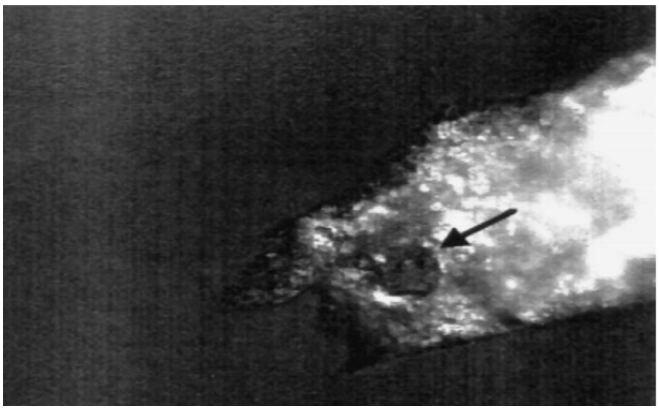


Figure 1: Polarized light micrograph of a granulation.

used to map chlorine content and reveal the distribution of the API in the granulation. These experiments demonstrate that the API exists as the hydrochloride salt in the granulation and retains its original particle size distribution; therefore, the high temperatures and drying conditions used in the manufacturing process do not appear to have negatively affected the drug substance [9,26].

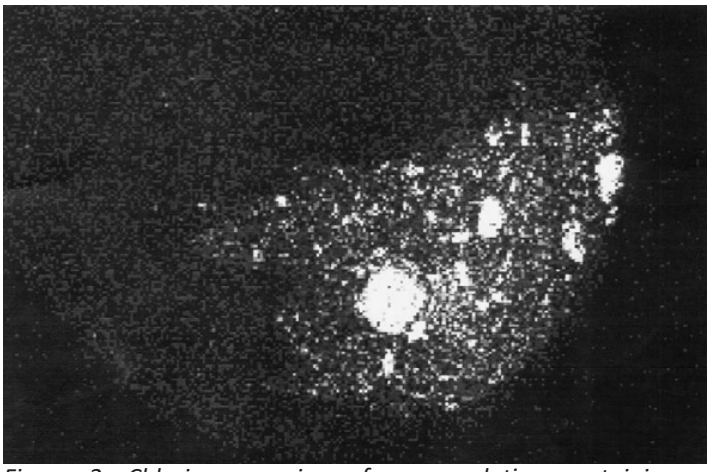


Figure 2: Chlorine mapping of a granulation containing a hydrochloride salt API.

X-Ray Powder Diffraction:

a. It is used to detect crystalline compound-lattice.

b. A collimated beam of X-rays is incident upon this lattice, X-rays are diffracted.

c. Every crystal own characteristic X-ray diffraction pattern

d. Technique is useful for: Distinguishing between solid state forms of a bulk drug substance (Distinguishing between polymorphs, hydrates, and solvate).

e. The technique is also useful for characterizing changes in the drug substance in a solid state as it exists in a matrix of a formulation for example, a change from a crystalline to an amorphous form or hydration, dehydration, etc.

f. A regulatory agency asked whether the polymorphic form of an API changed during the formulation process.

g. To answer this question, X ray powder diffraction patterns of crushed tablets, crushed placebo tablets, and three lots of the API were acquired [9,26].

Thermal Analysis: Thermo-gravimetric and differential thermal analysis (TG/DTA) are useful techniques for the solid-state characterization such as:

i. Determinations of loss on drying,

ii. Phase transition temperatures,

iii. Thermal stability, and

iv. Water is bound or unbound.

v. Idea about storage condition.

The TG/DTA data are derived from the response of the sample to a heating program. In DTA the sample temperature remains constant throughout an endothermic transition, whereas the sample temperature increases during an exothermic transition. ATG curve is simultaneously acquired, yielding the corresponding mass change curve. These dual pieces of information make interpretations more straightforward than interpretation with either technique alone. TG/DTA was utilized to monitor changes in the crystal morphology and physical changes of a hydrated API in a granulation blend and in tablets compressed from the blend [28].

Fourier Transform Infra-Red (FTIR) Micro spectroscopy: It is useful technique for the identification of the compound. It utilizes small sample for the analysis. When unidentified crystalline particles were found growing on tablets during a stability studyFTIR micro spectroscopy with a spectral resolution of about 5 µm was used to chemically analyze and identify the minute particles. FTIR spectrum of excised crystals found on tablets during a stability study. The crystals were identified as stearyl alcohol. Infrared spectroscopy is well established, and infrared spectra are considered to be definitive for identity testing in the pharmaceutical industry. FTIR micro spectroscopy, equipped with an automated stage, is a nondestructive technique that can be utilized to analyze 0small samples and to chemically map locations by identifying components within the sample [28].

NMR Spectroscopy: Understanding structural changes that occur in controlled release dosage forms as they

interact with physiological fluids is critical to understanding and predicting the performance of the product. As a result, noninvasive NMR imaging techniques have gained momentum in studies assessing the performance of solid oral dosage forms. One such study is of hydroxypropyl methylcellulose (HPMC) tablets that form a gel layer when the polymer matrix hydrates and swells. In an effort to understand the release of an API from controlled release tablets containing HPMC, NMR imaging techniques were used to measure the relaxation times and self diffusion coefficients (SDCs) of water across the gel layer [29].

Mass Spectrometry: Mass spectrometry (MS) is one of the most specific techniques available to the analytical chemist because the generation of molecular weight data coupled with fragmentation patterns is usually quite conclusive. The use of MSn often allows complete specificity, even in the presence of related substances, impurities, and pharmaceutical matrices [20-32]. This technique could be extremely important for assessing the controlled release properties of a solid oral dosage form. The homogeneity and quality of the manufacturing process could be determined. Also, this technique could be applied to the analysis of the surface of beads, tablets, and granulations, allowing the chemical composition of more than one layer to be evaluated [33].

Raman Spectroscopy: The advantages of using Raman spectroscopy for the analysis of the solid dosage forms of pharmaceuticals have been thoroughly documented [34]. The main problem in measuring the bulk composition of tablets or powders from Raman data is that the signals may not be representative of the composition of the sample as a whole because sampling errors will arise if the tablets are heterogeneous on length scales greater than the size of a typical focused laser spot [35,36].

Advancements in dispersive Raman spectroscopy, including improvements in detectors, filters, optical fibers, and instrument designs, have made this technique a readily accessible tool for the in situ and noninvasive determination of solid phase physical properties of the API in solid dosage forms. In addition, the relatively low energy light near the visible region lends itself well to the use of optical fibers, and Raman spectroscopy does not require any sample preparation. A spatial resolution of approximately 2µm is possible [37].

Near IR (NIR) Spectroscopy: There is intense interest in using NIR techniques in several major areas of pharmaceutical operations: clinical supply identification, incoming raw material. An NIR spectroscopic method to identify pharmaceutically active and Inactive (placebo) clinical dosage forms were recently developed typically, the dosage form is packaged with its placebo in the same blister pack. The purpose of the NIR identification method was to identify, nondestructively and rapidly, the four forms in the blister pack. The method was developed to create and validate a onetime use library of the spectra of clinical dosage forms prepared for double-blind clinical trials [9,26].

Automation

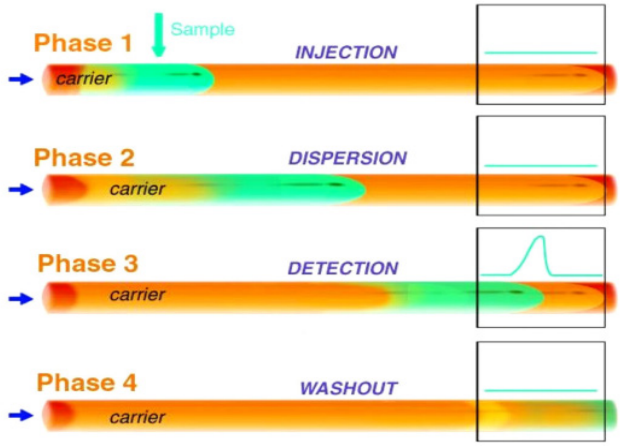
Fiber-Optic Dissolution System: IVIVC studies are expected for NDAs for solid oral extended release dosage forms. Regulatory agencies have an expectation that in vitro release (dissolution) testing should be used as more than a quality control test. SUPAC guidelines as well as guidance on extended-release dosage forms have placed an increasing emphasis on the dissolution test [38]. If an IVIVC has been demonstrated, SUPAC enables sponsors to make site, process, raw material source, and other changes in marketed products without expensive in vivo studies if the resulting dissolution profiles are shown to be equivalent. The dissolution test has been a labor and resource intensive test in need of modernization. In general, for controlled release products, 6 or 12 dissolution vessels are sampled periodically throughout a time period of up to 24 hours or more. Increasingly, dissolution profiles are expected for immediate release products as well. For the determination of IVIVCs the in vitro time periods ideally should correspond to the times of the in vivo measurements. The in vivo measurements may be every 10 or 15 minutes over the early course of a study and every half-hour thereafter.

The corresponding invitro measurements are not practical with conventional apparatus currently described in the compendia. In addition, the use of sippers, transfer tubing, and injectors (manual or otherwise) is not practical or reliable enough for these data collection rates. The complex equipment contains numerous moving parts that can malfunction and cause sampling errors. In addition, these systems are prone to dilution related errors, contamination, sample carryover, leaks, and blockage by air bubbles and particulate matter. Fortunately, automated fiber optic probe based dissolution systems have begun to appear for these solid dosage-form applications [39-44].

Flow Injection analysis: The ICH Quality Guidance Q6A states that synthesis impurities of the API are not required to be remeasured in the dosage form unless they degrade during the manufacturing process. This paves the way for the use of automated high throughput techniques, such as FIA, that are capable of up to 100 per hour or more. FIA systems capable of analyzing tablets are described in the

literature. This often includes spectrophotometric based detection, where there is little background interference [45,46]. With FIA, high sample throughputs are achievable with good results. The development of a system with good linear response capable of analyzing 40 paracetamol tablets per hour was reported. The basis of Flow injection analysis (FIA) is injection of a liquid sample into a moving, non-segmented uninterrupted carrier stream of a suitable liquid. The injected sample forms a zone, which is then transported toward a detector that uninterruptedly records the changes in absorbance, electrode potential, or other physical parameter resulting from the passage of the sample material through the flow cell [47].

Robotics and Laboratory Automation: To acquire the huge amounts of data required for pharmaceutical registrations, automated techniques have been developed and continuously improved over the past several decades. An early autoanalyzer technique employed continuous solution flow streams separated by air bubbles, and highly successful commercial systems were developed based upon this technique [48]. In recent years, however, these systems have fallen out of favor because of their complexity and high maintenance requirements. Over the last 30 years, robotic systems to automate manual laboratory techniques have become available. More recently, robotic systems have evolved that operate unattended and are capable of high throughput solid dosage form analysis with an accuracy and precision equivalent to their corresponding manual techniques. These systems initially suffered from faulty design, frequent breakdown, poor user interface, and complex programming requirements, but to a great extent, these faults have been overcome [49-52].



Source: http:// ww2.chemistry.gatech.edu/class/analyt/fia.pdf.

Figure 3: Stages of flow injection analysis.

Future directions

In the past century, there has been a tremendous growth in pharmaceutical analyses and the role the analytical group plays in the development of new products. The baton was passed from techniques such as gravimetry, titrimetry, spectroscopy after extraction, and thin layer paper chromatography to HPLC, gas chromatography, and various autoanalyzers. Emphasis was on tests such as assay, content and blend uniformity, and determination of impurities and residual solvents [53]. To produce affordable, quality medications, much of the routine test results will have to be produced by newer, high throughput techniques that generate huge volumes of data without analyst intervention. Chemometrics and expert" system will play a major role in the treatment and interpretation of the data. The analyst will have more choices regarding the bench-top analytical techniques and will have to ensure that the most efficient and meaningful body of data is collected [52].

Conclusion

The present review highlighted that the pharmaceutical solid dosage form and the role of analytical separation techniques. Transforming a drug into a proper dosage form is a very important milestone in the pharmaceutical industry for better therapeutic efficacy and bioavailability. The physical properties, the state of the drug substance in the matrix what makes the pharmaceutical analysis of finished solid oral dosage forms is a unique delivery form. During product development, many analytical techniques can be brought to bear, providing a characterization of the product and guiding the pathway to an optimum formula. Solid oral dosage forms easy to manufacture and stable, they are the most common form of self-medication. Immediate controlled and extended release solid oral dosage forms are easy to manufacture, reproducibly and provide convenient delivery systems for self-administered medications.

To design effective delivery systems, it is important to understand the behavior and characteristics of the active pharmaceutical ingredient (API) when it is incorporated into polymers that are used to modify its physical state or control its release in the gastrointestinal tract. These formulations often present considerable challenges to the pharmaceutical chemist. To facilitate the development of immediate-, controlled-, and extended release products and other types of solid dosage forms, noninvasive and nondestructive in situ techniques provide insight into the physical nature and microhomogeneity of the dosage form. These techniques include light microscopy, polarized light microscopy, scanning electron microscopy, transmission microscopy, Fourier transform infrared microspectroscopy, nuclear magnetic resonance imaging, near-infrared (NIR) analysis, Raman spectroscopy, thermal techniques, mass

Table 1: Typical Tablet and Capsule Specifications for Product Release and Stability Monitoring.

Test	Details	Required tests	
		Initial Analysis	Stability
Appearance of Product			
Tablets	To include color, shape, type of coating, markings, and printing	No	No
Capsules	To include capsule color, brittleness, printing, and description of contents	No	No
Appearance of package	Exterior and interior	No	No
Identification of Active Constituent s)	By two different methods, one of which includes confirmation of the salt, if any	No	
Assay of Active content (s)			
Uniformity of Contents (dose)	Between Individual dosage units, if required, depending upon dosage strength/weight	No	No
Degradation of Products	To include individual named, individual unnamed, and total	No	No
Residual Solvent (s) levels	Only if solvents were used	No	No
Dissolution (s)	Mean and individual values for six units for each active	No	No
Identification of dyes	If a dye is used	No	No
Dimensions			
Round tablets	Diameter and thickness	No	No
Shaped tablets	Thickness, length, breadth	No	No
Capsules	Capsule Size	No	No
Hardness	Tablets only	No	No
Average Weight			
Uniformity of Weight		No	No
Friability	Tablets only	No	No
Disintegration time		No	No
Microbial limits	Total Viable count for aerobic bacteria and yeast/molds, total Enterobacteria, absence of Pathogenic Enterobacteria, Pseudomonas aeruginosa, and Staphylococcus aureus	No	No
pH	For Soft gelatin capsules	No	No
Leakage	For Soft gelatin capsules	No	No
Pellicle Formation	For Soft gelatin capsules	No	No

spectrometry, and other imaging techniques. Therefore modern analytical techniques have a crucial role in the designing formulation, API characterization, invitro study, stability study, quality control of various pharmaceutical solid oral dosage forms for intended purpose.

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*Corresponding author: : Yesuneh Tefera Mekasha, Email: yetefera19@gmail.com