

A REVIEW ON AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE DRY SYRUP

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ABSTRACT

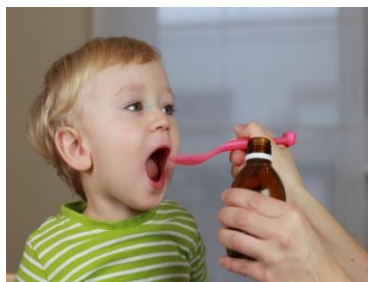
The advantages of oral dosage form that are responsible for its popularity are its ease of Administration, patient compliance and stability of formulation. The most popular oral dosage Forms beings tablets and capsules, but one important drawback of the dosage forms however is the difficulty to swallow especially when a dosage form is developed for pediatric and Geriatric patient. The modern scientific and technological advancement in the pharmaceutical Field had created bank of interest in reconstitutable oral suspension dosage form in the recent Year. The reconstituted system is the formulation of choice when the drug stability is a major Concern. Reconstitutable oral systems show the adequate chemical stability of the drug during Shelf life and also reduce the weight of the final product. Dry syrup form of the drug is also useful in case of bioavailability as it has high bioavailability rather than tablets and capsules as it disintegrates in water outside of the oral cavity and directly the suspension is gone through the gastrointestinal tract, so the suspension easily absorbs in the GIT.

KEYWORDS: Dry Syrup, Patient Compliance, Antibiotic, Amoxicillin, Stability, Sedimentation Volume, Reconstituted Dry syrup.

INTRODUCTION^[1-32]

Oral dosage forms, including Amoxicillin Trihydrate dry syrups, are favored for their ease of administration, stability, and patient compliance. Antibiotics like Amoxicillin are often formulated as dry powders for reconstitution due to their instability in liquid form, especially over extended periods. This formulation offers enhanced stability, making it a preferred choice for paediatric and geriatric care. Many antibiotics are unstable in solutions, making insoluble forms in aqueous suspensions or dry powder for reconstitution more attractive for manufacturers. Among these, the combination of amoxicillin and clavulanate potassium has gained significant attention. Amoxicillin is a penicillin derivative antibiotic used to treat infections in the respiratory, gastrointestinal, and urinary tracts. Clavulanate potassium, a salt of clavulanic acid, inhibits penicillinase and β -lactamase, enhancing the efficacy of amoxicillin. According to the World Health Organization (WHO), β -lactam antibiotics with β -lactamase inhibitors are high-priority drugs due to their lower resistance potential and frequent use for various indications. They are recommended as first-choice medicines for treating respiratory tract diseases, pneumonia, and chronic obstructive pulmonary disease (COPD). The combination of amoxicillin and clavulanate has been

widely used since its introduction in clinical medicine in Europe in 1981 and the United States in 1984. It is commonly prescribed for patients of all ages, including infants, children, and adults, due to its desirable antibacterial spectrum, favorable pharmacokinetic profiles, and safety. Drug stability is vital for maintaining potency and physical characteristics. Factors affecting stability include temperature, light, humidity, and packaging. Quality of drugs is maintained by developing highly accurate and precise analytical methods that meet validation parameters. Amoxicillin remains significant in treating Helicobacter pylori-associated gastritis and various other infections, including intra-abdominal, lower urinary tract, and skin infections. The combination of amoxicillin and clavulanate continues to play a vital role in the medical field due to its broad-spectrum efficacy and safety profile.



Dry Syrup^[33-41]

Dry syrups are pharmaceutical formulations containing finely divided, insoluble particles (0.5–5 μm) that require reconstitution with water before oral administration. These are particularly suitable for antibiotics and moisture-sensitive drugs, often used in pediatric treatments. Dry pharmaceutical syrups are solid dosage forms that can be reconstituted with water for oral administration. Examples include Amoxicillin trihydrate, Erythromycin ethyl succinate, and Dicloxacillin sodium. The reconstituted systems, which consist of drug, colorants, flavors, sweeteners, stabilizing agents, suspending agents, and preservatives, are preferred when drug stability is a concern. Reconstituted dry syrups remain stable for a specified period when stored under recommended conditions. Reconstituted forms typically have a shelf life of 7–14 days, depending on storage conditions like temperature and pH. Challenges like Errors in reconstitution (incorrect volume, temperature, or storage) can affect drug efficacy. Unused portions of reconstituted syrups should be discarded to avoid using degraded medication.



Fig. 1: Amoxicillin & Potassium Clavulanate Dry Syrup.

Major application

Pediatric therapy (Taste Masking): Oral Route of administration is the route of choice for administration of medicines in children. The only hurdle for dosage form designing for pediatric patients is the patient's

acceptance of the dosage form. Pediatric Patients tend to become uncooperative during the administration of oral medication; the most common reason being the taste of the oral formulation administered among the children. Most of the drugs administered as granules for oral suspension under pediatric therapy are Antibiotics, which when administered orally as any other dosage form have a bitter taste making it unpleasant for Children to consume the medication.

Advantages of dry Syrup

- There is accurate single dosing as the dose is packed in single dose sachets.
- Drug dose is comparatively independent of any physical factors like temperature, sedimentation rate and liquid flow properties.
- The packaging of the powder mixture is done in sachets making the formulation easy to carry.
- The enhanced convenience of the single dosage regimen.
- Colored, flavored, sweetened formulation is advantageous for administration to the paediatric population.
- Stable on storage and when reconstituted with an ingestible liquid for administration, the corresponding liquid suspension is stable for the duration for which the therapy is required.

Disadvantages of Dry Syrup

- It is a bulk formulation, so there are chances of inaccuracy in single dosing.
- Drug dose depends on various physical factors of the dosage form such as the temperature of storage, sedimentation rate of the formulation, liquid flow properties like viscosity, pourability, redispersion, flocculation and content uniformity.
- Stability of the liquid largely depends on the temperature of storage.
- Caking occurs upon storage

Amoxicillin is a penicillin antibiotic. It is used to treat bacterial infections, such as chest infections (including pneumonia) and dental abscesses. It can also be used together with other antibiotics and medicines to treat stomach ulcers.

The following table shows the brand name of Amoxicillin Trihydrate and Clavulanate potassium dry syrup with its manufacturer and amount of API (per 5 ml).

Table 1: Branded drugs and Manufacturer.

Sr. No.	Brand Name	Manufacturer	Form	Amount of API (per 5 mL)
1	Augmentin	GlaxoSmithKline (GSK)	Dry Syrup	125 mg Amoxicillin, 31.25 mg Clavulanate Potassium
2	Co-Amoxiclav	Sandoz	Dry Syrup	200 mg Amoxicillin, 28.5 mg Clavulanate Potassium
3	Clavamox	Himalaya	Dry Syrup	200 mg Amoxicillin, 28.5 mg

				Clavulanate Potassium
4	Amoclav	Alkem Laboratories	Dry Syrup	200 mg Amoxicillin, 28.5 mg Clavulanate Potassium
5	Amoclav-DS	Abbott Laboratories	Dry Syrup	250 mg Amoxicillin, 62.5 mg Clavulanate Potassium
6	Amoxi-Clav	Cipla	Dry Syrup	125 mg Amoxicillin, 31.25 mg Clavulanate Potassium
7	Clavumox	Dr. Reddy's Laboratories	Dry Syrup	125 mg Amoxicillin, 31.25 mg Clavulanate Potassium
8	Clavocin	Lupin Pharmaceuticals	Dry Syrup	200 mg Amoxicillin, 28.5 mg Clavulanate Potassium
9	Amoclav Plus	Emcure Pharmaceuticals	Dry Syrup	250 mg Amoxicillin, 62.5 mg Clavulanate Potassium
10	Co-Amoxyclav	Sun Pharma	Dry Syrup	200 mg Amoxicillin, 28.5 mg Clavulanate Potassium
11	Clavarin	Intas Pharmaceuticals	Dry Syrup	125 mg Amoxicillin, 31.25 mg Clavulanate Potassium
12	Amoclan	Biocon	Dry Syrup	200 mg Amoxicillin, 28.5 mg Clavulanate Potassium
13	Clavicle	Sanofi Aventis	Dry Syrup	125 mg Amoxicillin, 31.25 mg Clavulanate Potassium

MATERIALS AND METHODS^[42-47]

Materials

- 1) Amoxicillin Trihydrate
- 2) Potassium Clavulanate
- 3) Xanthan Gum
- 4) Dextrose
- 5) Silicon Dioxide
- 6) Starch
- 7) Venilla

1) Amoxicillin Trihydrate

Amoxicillin is a penicillin-class antibiotic widely used to treat various bacterial infections. It is effective against a range of conditions and works by inhibiting bacterial growth. Used in Primary Infections such as Chest infections (e.g., pneumonia), Dental abscesses, Bacterial respiratory, urinary, and gastrointestinal infections. Used alongside other medications to treat stomach/intestinal ulcers caused by *Helicobacter pylori*. Prevents recurrence of such ulcers.

Amoxicillin Is FDA Approved to Treat

- Bacterial Pharyngitis
- Bronchitis
- Tonsillitis
- Pneumonia
- Bacterial Rhinosinusitis

2) Clavulanate potassium

Clavulanic acid is a combination penicillin-type antibiotic used to treat a wide variety of bacterial infections. It works by stopping the growth of bacteria. These antibiotic treats only bacterial infections. It will not work for viral infections (such as common cold, flu). Using any antibiotic when it is not needed can cause it to not work for future infections. very serious allergic reaction to this drug is rare. However, get medical help

right away if you notice any symptoms of a serious allergic reaction, including: fever that doesn't go away, new or worsening lymph node swelling, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

3) Xanthan gum: Commonly used thickening and stabilizing agent in various pharmaceutical formulations, including dry syrups. Here are some key roles of guar gum in dry syrup preparations.

Thickening agent: Guar gum helps to increase the viscosity of the syrup, giving it a smooth and uniform consistency. This aids in suspending the active ingredients evenly throughout the formulation and prevents settling.

Stabilizer: Guar gum acts as a stabilizer by preventing the separation of ingredients in the dry syrup powder. It helps maintain the homogeneity and uniform dispersion of the components, ensuring consistent dosing.

Improves flow properties: Guar gum can improve the flow properties of the powder, making it easier to handle and dispense. It helps prevent clumping and caking, resulting in a more user- friendly product.

Enhances texture: Guar gum contributes to the overall texture of the dry syrup powder, providing a pleasant mouthfeel when reconstituted with water. It can help improve the overall palatability of the formulation.

Binding agent: Guar gum can act as a binding agent, helping to hold the ingredients together in the dry syrup powder. This is important for ensuring the stability and integrity of the formulation during storage and handling.

4) Dextrose

Uses: Dextrose, also known as glucose, is a simple sugar commonly used in various applications. It is often used as an energy source, a sweetener, or a stabilizer in food products. In the medical field, dextrose is used in intravenous solutions for patients requiring quick energy, and in the laboratory, it serves as a carbon source for microorganisms in culture media. Dextrose is derived from natural sources like corn or wheat and is considered safe for consumption.

5) Silicon Dioxide: Silicon Dioxide used as anti-caking agent.

6) Starch

1. Binder: Starch can act as a binder to hold the ingredients of the dry syrup together, ensuring that the powder remains cohesive and does not separate or clump during storage or transportation.

2. Disintegrant: Starch can help promote the disintegration of the dry syrup in liquid when it is reconstituted, allowing for quick and uniform mixing to form a suspension for administration.

7) Flavoring Agent

Vanilla is a popular flavoring agent that is often used in dry syrup formulations to improve the taste and palatability of the medication. In addition to masking the unpleasant taste of certain active ingredients, vanilla can also enhance the overall sensory experience of taking a medication, especially for individuals who may have difficulty swallowing pills or find the taste of some medications unappealing. The use of vanilla in dry syrups can help make the medication more pleasant to take, leading to better adherence to the prescribed treatment regimen. It can also help reduce the likelihood of adverse reactions such as nausea or vomiting that may be triggered by an unpleasant taste.



Method of preparation of dry mixture

Dry syrup is manufactured in three methods namely

1. Direct Mixing,
2. Dry Granulation (Slugging) and
3. Wet Granulation (wet massing)

1. Flow Chart of Direct Mixing

Process of direct mixing is summarized in fig. 2.

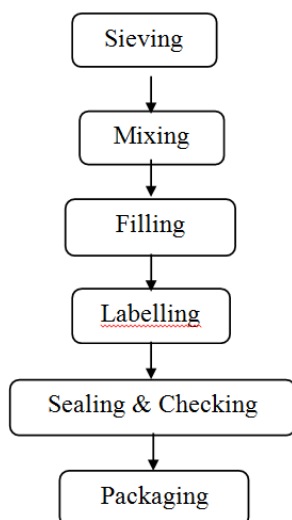


Fig. 2: Direct Mixing.

2. Flow chart of dry granulation

Process of dry granulation is shown in fig 3.

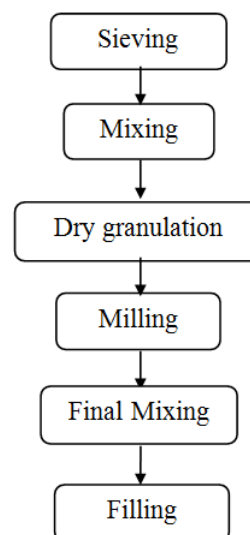


Fig. 3: Dry granulation process.

3. Flow chart of wet granulation

Wet granulation is one of the methods of preparation of dry syrup which is shown in fig. 4.

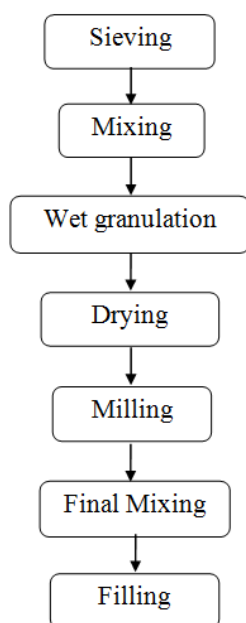


Fig. 4: Wet granulation.

Preparation of dry mixture^[48-50]

- 1 Direct mixing
- 2 Granulated products
- 3 Combination products

1 Direct mixing

The selection of the appropriate mixer involves several considerations, the most significant of which is that the mixer should rapidly and constantly produce a homogenous mixture.

Direct mixing Process of direct mixing with their advantages and disadvantages shown in table.

Table 2: Direct mixing.

Powder blender	Advantages	Disadvantages
Also called powder mixtures, are prepared by mixing the Excipients of dry mixture in powder form. Excipients Present in small quantities may require a two-stage mixing operation.	Least capital equipment and energy Less chemical & physical stability problems because no heat or solvents are used.	Loss of active ingredient during mixing. Prone to homogeneity problem.

The equipment used is mixers. Few types of mixers are discussed below

1. Dry mixer
2. Paddle mixer
3. Vertical screw mixer
4. Double cone mixer
5. V blender

Combination product

Powdered and granulated excipients can be combined to overcome some disadvantages of granulated products. Less energy and equipment for granulation may be required if the majority of the diluents can be added after

granulation. Also heat sensitive excipients such as flavors can be added after drying of the granulation to avoid exposure to elevated temperatures. The general method is first to granulate some of the excipients, then blending the remaining excipients with the dried granules before filling the container. The presence of the diluents helps to improve flow and reduces both segregation and dust formation.

Disadvantages

1. Risk of non-uniformity
2. Particle sizes of various fractions should be carefully controlled.

Advantages and Disadvantages of types of Dry mixtures^[48-50]

Table 3: Advantages and disadvantages of dry mixtures.

Types	Advantages	Disadvantages
Powder blend	Economical & Low incidence of Instability	Mixing & segregation Problems Losses of drugs
Granulated products	Good Appearance, Flow characteristics, Less segregation & Less dust	Cost Effects of heat, granulating fluid on drug & excipients
Combination product	Reduced cost & Use of heat sensitive ingredients	Ensuring non segregating mix of granular & nongranular ingredients

Condition for manufacturing Dry Syrup^[45]

For manufacturing of dry syrup following conditions should be maintained.

1. Relative humidity: Not more than 60%.

2. Temperature: Below 25°C
3. All relevant materials are removed
4. Equipment is cleaned
5. Balanced is calibrate.

*When reconstituted, each 5 mL contains: AMOXICILLIN, 600 mg, as the trihydrate
 CLAVULANIC ACID, 42.9 mg (equivalent to 51.1 mg of clavulanate potassium).
 Potassium Content 0.248 mEq per 5 mL
 Net Contents: Equivalent to 15 g amoxicillin and 1.0725 g clavulanate acid.
 Store dry powder at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
 Directions for mixing:
 1. Tap bottle until all powder flows freely.
 2. Measure "10" mL of water (total).
 3. Add approximately 2/3 of the water to powder. Replace cap; shake vigorously.
 4. Add rest of the water. Replace cap; shake vigorously.
 DOSAGE: See accompanying prescribing information.
 Phenyleketonurics: Contains phenylalanine 7 mg per 5 mL.
 Use only if inner seal is intact.
 Keep tightly closed. Shake well before using. Must be refrigerated.
 Date reconstituted: ___/___/___
 Discard after 10 days.
 Some color change is normal during dosing period.

NDC 0143-9853-16
Amoxicillin and Clavulanate Potassium
 For Oral Suspension, USP
600 mg/42.9 mg per 5 mL*
 125 mL (when reconstituted)
 KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
 Manufactured by: Hikma Pharmaceuticals
 PO Box 182400, Amman, 11118 - Jordan
 Distributed by: Hikma Pharmaceuticals USA Inc.
 Berkeley Heights, NJ 07922
 R_x only
 hikma.

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Evaluation of oral reconstitute suspension^[43,49,51]

After preparation of reconstitutable suspension, it will evaluate for below parameters.

- Flow properties:** Flow properties such as angle of repose, bulk density, tap density and porosity of powder mixture, granulations and combination product should be carried out.
- Rheological behavior:** The rheological behavior of the reconstituted suspensions is determined using Brooke field viscometer (Model – RVT).

3. Sedimentation behavior: a.) Redispersibility: The redispersibility is determined by studying the number of strokes to redisperse the formed sediment at the end of 7 days of storage of the formulations (not more than 100 strokes = Redispersibility). b.) Sedimentation Volume Ratio (SVR): Sedimentation volume of a suspension is expressed by the ratio of the equilibrium volume of the sediment, V_u , to the total volume, V_o of the suspension i.e. $F = V_u/V_o$.

The value of F normally lies between 0 to 1 for any pharmaceutical suspension. The value of F provides a qualitative knowledge about the physical stability of the suspension.

4. Drug content: The required weight of drug mixture is taken and extracted with 100ml solvent and solution is filtered through nylon filter membrane. 0.1ml of the solution is further diluted to 10ml with solvent and absorbance of the solution is read on UV Spectroscopy. The drug concentration is extrapolated from the calibration curve in solvent.

Expected Value: The content should be between 90% to 110% of the labeled claim.

5. In vitro drug release: The in vitro dissolution studies were carried out using USP apparatus Type II at 100 rpm. The dissolution medium consisted of 900 ml distilled water maintained at $37^\circ\text{C} \pm 0.50$ C. The drug release at different time intervals was measured for two hours using UV spectrophotometer.

6. Particle size: The oral reconstitutable suspension is evaluated, the average particle size of the formulation is

examined using standard microscopy method average and standard deviations of 100 particles are estimated.

7. Viscosity: The rheological behavior of the suspension is determined by using Brookfield viscometer (Model - LVDI).

8. Zeta potential measurement: Suspension is diluted with distilled water and the measurements are taken in triplicate.

9. Stability study: The reconstitutable suspension is stored in air tight amber colored glass bottles for 36 days at 45°C and then reconstituted with distilled water to make up the volume to 60 ml with gentle shaking. The reconstituted suspension is stored at 4°C , 25°C and 45°C for 15 days. (10) pH values: The pH of suspensions was measured with the aid of a pH meter.

10. pH: Expected pH Range: After reconstitution, amoxicillin dry syrup should fall within a pH range of 4.0-7.0.

11. Reconstitution and Taste

Reconstitution Time: Should dissolve or suspend easily upon adding water.

Taste and Odor: Should have an acceptable flavor for pediatric use, such as fruit or sweet flavor.

12. Bulk density

The powder (2 gm) filled in measuring cylinder called as bulk volume of powder and measure mass of that powder. Bulk density is ratio of mass of powder to Bulk volume of powder. It is a measure used to Describe a packing of powder. The equation for Determining bulk density is
 $P_b = m/v_b$

Where, p_b = Bulk density
 m = Mass of powder
 v_b = Volume of powder.

13. Tapped density

The pre-weighed powder (2gm) was filled in Measuring cylinder. Then it was tapped in bulk Density test

apparatus. After 50 taps the volume is Measured and the tapped density was measured Using following formula.

$$Pt = m / vt$$

Where, ρ_t = Tapped density

m = Mass of powder

vt = Tapped volume.

14. Carr's index

Compressibility is indirectly related to the relative Flow rate, cohesiveness and particle size distribution of the powder. Powders with compressibility values Lesser than about 20%, has been found to exhibit good flow properties. Tapped (ρ_t) and Apparent (ρ_b) Bulk density measurements can be used to estimate the compressibility of a material

$$\text{Carr's index (\%)} = (\rho_t - \rho_b) / \rho_t * 100$$

Where, ρ_b = Bulk density

ρ_t = Tapped density

Packaging and storage^[43]

Dry powder for reconstitution packaged in wide mouth container or in sachet in case of unit dosing.

1. The dry powders for reconstitution should be packaged in wide mouth container having sufficient air space above the liquid.
2. The dry powders should be stored in tight container protected from freezing, excessive heat and light.
3. The label should contain the direction stating: "Shake Before Use" to ensure uniform distribution of solid particles and thereby to obtain uniform and proper dosage.
4. The dry powders should be stored at room temperature.
5. After reconstitution the suspension should be stored in the refrigerator (freezing should be avoided to prevent aggregation)
6. For single dosage packing, sachets are used made up of 4 layers of aluminum foil.

Labelling

- That the contents are meant for preparation of an oral liquid.
- The directions for preparing the oral liquid including nature and quantity of liquid to be used.
- The conditions under which the reconstituted solution should be Stored.
- The period during which the constituted oral liquid may be Expected to remain satisfactory for use when prepared and stored in Accordance with manufacturer's recommendations.
- The strength in terms of active ingredients in a suitable dose Volume of reconstituted preparation.

CONCLUSION

Amoxicillin Trihydrate dry syrup is a widely used antibiotic formulation, especially effective for pediatric patients. Its combination with clavulanic acid enhances its effectiveness against resistant bacteria. Dry syrups offer benefits such as ease of administration, stability and

improved taste, making them ideal for children. The formulation focuses on maintaining the drug's potency, ensuring accurate dosing, and improving patient compliance, particularly in treating respiratory, gastrointestinal, and urinary infections.

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