FORMULATION HANDBOOK



4282-023

Acetylsalicylic Acid Effervescent Tablet Direct Compression

Acetylsalicylic Acid, Direct Key Words:

Compression, Effervescent Tablet

JRS Products: EMDEX®, PRUV®

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Summary

Acetylsalicylic Acid (ASA) is an old and very well known API substance with analgesic and antipyretic properties. It is a non-steroidal anti-inflammatory drug that also inhibits platelet aggregation.

Its lipophilicity and low water solubility make the development of an effervescent formulation challenging. For effervescents, dosages of Acetylsalicylic Acid between 300 and 800 mg are common.

Formulation

| | Active content [mg] | mg/tablet | Contribution [%] |
|---------------------------------|---------------------|-----------|------------------|
| Acetylsalicylic Acid (ASA) | 500.0 | 500.0 | 12.5 |
| PRUV® (Sodium Stearyl Fumarate) | | 12.0 | 0.3 |
| Citric Acid | | 348.0 | 8.7 |
| NaHCO ₃ | | 400.0 | 10.0 |
| Glycine HCI | | 128.0 | 3.2 |
| Aspartame | | 76.0 | 1.9 |
| Flavor | | 36.0 | 0.9 |
| EMDEX® (Dextrates) | | 2,500.0 | 62.5 |
| Total | | 4,000.0 | 100.0 |

Procedure

Blending:

All ingredients except PRUV® were blended for 15 minutes. PRUV® was added and the powder mixture was mixed for another 3 minutes. The powder mixture was ready for direct compression.

| Equipment: | | |
|------------------------|---------------------------|--|
| Tablet Press: | Korsch EK 0, instrumented | |
| Turbula Mixer: | Type T2A | |
| Tablet Diameter: | 25 mm, biplane | |
| Hardness Tester: | Schleuniger 2E | |
| Disintegration Tester: | Pharmatest Standard PTZ | |
| Dissolution Tester: | Pharmatest PTW 2 | |
| Spectrophotometer: | Cecil CE 1021 | |

Tablet Characteristics

| Compression Force: | 20 kN |
|----------------------|-------|
| Crushing Strength: | 100 N |
| Diameter: | 25 mm |
| Disintegration Time: | 180 s |



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Dissolution Test:

Acetylsalicylic Acid

Effervescent Tablet Direct Compression

Dissolution Medium:

900 mL 0.1 N HCl, 37 °C, n=6

Samples were taken after 5, 10, 15, 30, 60, 120, 180 and 300 minutes. The sample volume was 3 mL. The samples were diluted if necessary. The determination of the Acetylsalicylic Acid was done by an UV-spectrophotometer at $\lambda = 232$ nm.

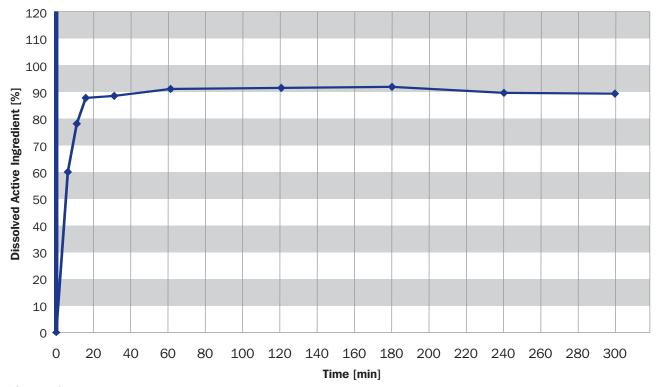


Diagram 1:

Dissolution profile of Acetylsalicylic Acid 500 mg effervescent tablet. Produced according to the above formulation.

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