

# 4282-056

**Key Words:** Hydrochlorothiazide, Low Water-solubility, Direct Compression

## Hydrochlorothiazide Direct Compression

**JRS Products:** PROSOLV® EASYtab SP

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### Summary

Hydrochlorothiazide belongs to the class of thiazide diuretics prescribed to treat high blood pressure and edema (i.e., swelling due to fluid retention, associated with poor heart, liver, or kidney function). It works by reducing the resorption of

electrolytes (mineral salts) by the kidneys. This results in increased urine output, which, in turn, lowers fluid volume throughout the body. Reduced blood volume causes blood pressure to drop. The dosage of Hydrochlorothiazide varies from 10 to 25 mg.

### Formulation

|                            | Active content [mg] | mg/tablet | Contribution [%] |
|----------------------------|---------------------|-----------|------------------|
| Hydrochlorothiazide        | 25.0                | 25.0      | 12.5             |
| <b>PROSOLV® EASYtab SP</b> |                     | 175.0     | 87.5             |
| Total                      |                     | 200.0     | 100.0            |

### Procedure

#### Blending:

The API was blended with **PROSOLV® EASYtab SP** for 15 minutes. The powder mixture was ready for direct compression.

#### Equipment:

|                     |                              |
|---------------------|------------------------------|
| Tablet Press:       | Kilian Pressima              |
| Turbula Mixer:      | Type T2A                     |
| Hardness Tester:    | Schleuniger Tablet Tester 6D |
| Dissolution Tester: | Pharmatest PTW 2             |
| Spectrophotometer:  | Cecil CE 10221               |

### Tablet Characteristics

|                      |        |
|----------------------|--------|
| Compaction Force:    | 3 kN   |
| Tablet Diameter:     | 8 mm   |
| Tablet Weight:       | 200 mg |
| Crushing Strength:   | 70 N   |
| Friability:          | 0.0 %  |
| Disintegration Time: | 10 s   |

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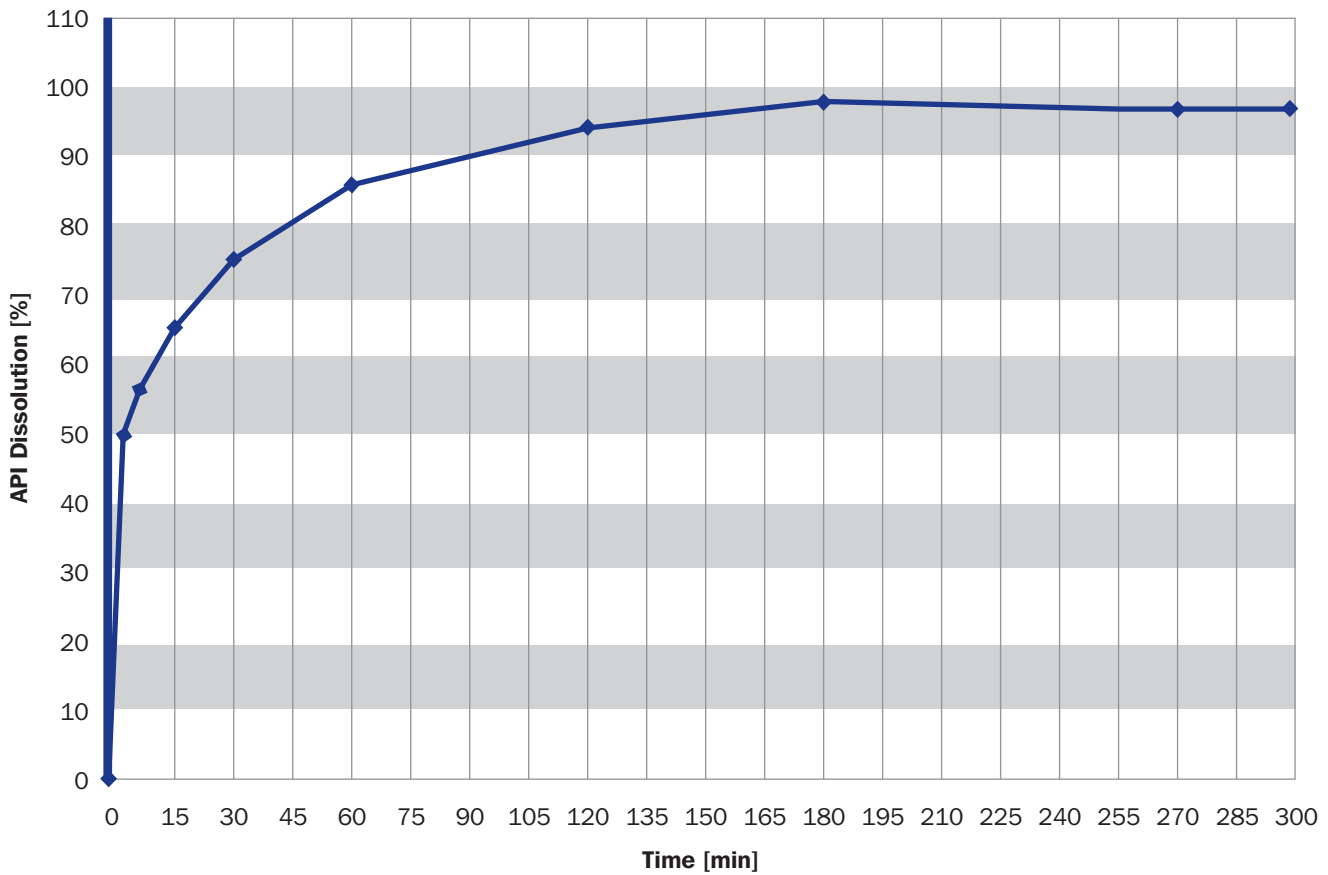
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### Dissolution Test:

Dissolution Medium: 900 mL 0.1 N HCl, 37°C, n=6

Samples were taken after 5, 10, 15, 30, 60, 120, 180, 270 and 300 minutes.

The determination of the Hydrochlorothiazide was done by UV spectroscopy at  $\lambda = 254$  nm.



**Diagram 1:**

Typical dissolution profile diagram of a Hydrochlorothiazide tablet. Produced according to the above formulation.

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