



Edition: BP 2025 (Ph. Eur. 11.6 update)

Hydrotalcite Tablets

[General Notices](#)

Action and use

Antacid.

DEFINITION

Hydrotalcite Tablets contain Hydrotalcite.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of hydrotalcite, $\text{Al}_2\text{Mg}_6(\text{OH})_{16}\text{CO}_3 \cdot 4\text{H}_2\text{O}$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Add 20 mL of [2M hydrochloric acid](#) to a quantity of the powdered tablets containing 1.0 g of Hydrotalcite, shake and filter. Add 30 mL of [water](#) to the filtrate and boil. Add 2M [ammonia](#) until just alkaline to [methyl red](#), continue boiling for 2 minutes and filter. Wash the precipitate with 50 mL of a hot 2% w/v solution of [ammonium chloride](#) and dissolve in 15 mL of [2M hydrochloric acid](#). The resulting solution yields the reaction characteristic of *aluminium salts*, [Appendix VI](#).

Neutralising capacity

Weigh and powder 20 tablets, pass the powder as completely as possible through a sieve of nominal mesh aperture about 225 µm and remix the sifted powder. Mix a quantity equivalent to one tablet with a small quantity of [water](#), added slowly with stirring, to give a smooth paste and add gradually sufficient further quantities of [water](#) to produce 100 mL. Warm to 37°, add 100 mL of [0.1M hydrochloric acid VS](#) previously heated to 37° and stir continuously using a paddle stirrer at a rate of about 200 revolutions per minute, maintaining the temperature at 37°. The pH of the solution at 37°, after 10 minutes and after 20 minutes, is 3.0 to 4.2, [Appendix V L](#). Add 12 mL of [0.5M hydrochloric acid VS](#) at 37°, stir continuously for 1 hour, maintaining the temperature at 37°, and titrate with [0.1M sodium hydroxide VS](#) to pH 3.5. Subtract the number of mL of [0.1M sodium hydroxide VS](#) from 160 mL to obtain the number of mL of [0.1M hydrochloric acid VS](#) required for neutralisation. Not less than 130 mL of [0.1M hydrochloric acid VS](#) is required to neutralise one tablet.

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 0.3 g of Hydrotalcite add 2 mL of 7M [hydrochloric acid](#) and heat on a water bath for 15 minutes. Allow to cool, add 250 mL of [water](#) and 50 mL of 0.05M [disodium edetate VS](#) and neutralise with 1M [sodium hydroxide](#) using [methyl red solution](#) as indicator. Heat the solution on a water bath for 30 minutes and allow to cool. Add 3 g of [hexamine](#) and titrate the excess of disodium edetate with 0.05M [lead nitrate VS](#) using [xylenol orange solution](#) as indicator. Each mL of 0.05M [disodium edetate VS](#) is equivalent to 15.09 mg of $\text{Al}_2\text{Mg}_6(\text{OH})_{16}\text{CO}_3 \cdot 4\text{H}_2\text{O}$.

