buffer solution (1 in 2) to make exactly $V$ mL so that each 
mL of the filtrate contains about 10 $\mu$g of imipramine 
hydrochloride ($C_{19}H_{22}N_2.HCl$) according to the 
labeled amount, and use this solution as the sample solution. 
Separately, weigh accurately about 0.025 g of Imipramine 
Hydrochloride Reference Standard, previously dried at 
105°C for 2 hours, dissolve in diluted pH 6.8 phosphate 
buffer solution (1 in 2) to make exactly 100 mL. Pipet 4 mL 
of this solution, add diluted pH 6.8 phosphate buffer 
solution (1 in 2) to make exactly 100 mL, and use this solution as 
the standard solution. Determine the absorbances, $A_T$ and 
$A_S$, of the sample solution and the standard solution at 250 
nm as directed under the Ultraviolet-visible Spectrophotometry. 

The dissolution rate of Imipramine Hydrochloride 
Tablets in 60 minutes should be not less than 75%. 

Dissolution rate (%) with respect to the labeled amount of 
imipramine hydrochloride ($C_{19}H_{22}N_2.HCl$) 

$$W_S = \frac{A_T}{A_S} \times \frac{V'}{V} \times \frac{1}{C} \times 36$$

$W_S$: Amount (mg) of Imipramine Hydrochloride Refer-
ence Standard.

C: Labeled amount (mg) of imipramine hydrochloride 
($C_{19}H_{22}N_2.HCl$) in 1 tablet.

Assay Take 20 Imipramine Hydrochloride Tablets, add ex-
actly 200 mL of 0.01 mol/L hydrochloric acid TS, and 
shake well until the tablets are completely disintegrated. Af-
fter centrifuging the solution, pipet a volume of the super-
natant liquid, equivalent to about 0.025 g of imipramine 
hydrochloride ($C_{19}H_{22}N_2.HCl$) according to the labeled 
amount, add 0.01 mol/L hydrochloric acid TS to make ex-
actly 100 mL, and use this solution as the sample solution. 
Separately, weigh accurately about 0.025 g of Imipramine 
Hydrochloride for Assay, previously dried at 105°C for 2 
hours, dissolve in 0.01 mol/L hydrochloric acid TS to make 
exactly 100 mL, and use this solution as the standard solu-
tion. Pipet 3 mL each of these solutions into separators 
which contain 15 mL of potassium hydrogen phthalate 
buffer solution, pH 5.6, 8 mL of brom cresol green-sodium 
hydroxide TS and 30 mL of chloroform, and shake. Filter 
the chloroform layer through a pledget of absorbent cotton 
into a 100-mL volumetric flask. Repeat the extraction with 
two 30-mL portions of chloroform, combine the chloro-
form layers in the 100-mL volumetric flask, and add chlor-
roform to make exactly 100 mL. Perform the test with these 
solutions as directed under the Ultraviolet-visible Spec-
tralphotometry, using a solution obtained by proceeding 
with 3 mL of 0.01 mol/L hydrochloric acid TS in the same 
manner as the blank. Determine the absorbances, $A_T$ and 
$A_S$, of these solutions at 416 nm.

Amount (mg) of imipramine hydrochloride ($C_{19}H_{22}N_2.HCl$) 

$$= \frac{A_T}{A_S}$$

Containers and storage Containers—Tight containers.

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**Imipramine Hydrochloride Tablets**

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Imipramine Hydrochloride Tablets contain not less 
than 93% and not more than 107% of the labeled 
amount of imipramine hydrochloride ($C_{19}H_{22}N_2.HCl$: 
316.87).

Method of preparation Prepare as directed under Tablets, 
with Imipramine Hydrochloride.

Identification (1) Weigh a quantity of powdered Imipa-
mine Hydrochloride Tablets, equivalent to 0.25 g of Imipa-
mine Hydrochloride according to the labeled amount, add 
25 mL of chloroform, shake thoroughly, and filter. 
Evaporate the filtrate on a water bath, and proceed with 
the residue as directed in the Identification (1) under Imipa-
mine Hydrochloride.

(2) Dissolve an amount of the residue obtained in (1), 
equivalent to 5 mg of Imipramine Hydrochloride, in 250 mL 
of 0.01 mol/L hydrochloric acid TS, and determine the ab-
sorption spectrum as directed in the Ultraviolet-visible 
Spectrophotometry; it exhibits a maximum between 249 nm 
and 253 nm, and a shoulder between 270 nm and 280 nm.

(3) Dry the residue obtained in (1) at 105°C for 2 hours: 
the residue melts between 170°C and 174°C (with decom-
position).

Dissolution test Perform the test with 1 tablet of Imipra-
mine Hydrochloride Tablet at 75 revolutions per minute 
according to Method 2 under the Dissolution Test, using 900 
ML of diluted pH 6.8 phosphate buffer solution (1 in 2) 
as the test solution. Take 20 mL or more of the dissolved 
solution after 60 minutes from the start of the dissolution test, 
and filter through a membrane filter with pore size of not 
more than 0.8 $\mu$m. Discard the first 10 mL of the filtrate, 
pipet the subsequent $V$ mL, add diluted pH 6.8 phosphate 

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(11:7:1:1) to a distance of about 12 cm, and air-dry the 
plate. Spray evenly potassium dichromate-sulfuric acid TS 
on the plate: the spots other than the principal spot from the 
sample solution are not more intense than the spot from the 
standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.3 g of Imipramine 
Hydrochloride, previously dried, and dissolve in 20 mL of 
water. Add 5 mL of sodium hydroxide TS, and extract with 
three 20-mL portions of chloroform. Filter each extract 
through a pledget of absorbent cotton on which a small 
quantity of anhydrous sodium sulfate is placed. Combine 
the chloroform extracts, and titrate with 0.1 mol/L per-
chloric acid VS until the yellow solution changes to red-pu-
ple (indicator: 10 drops of metanil yellow TS). Perform a 
blank determination.

Each mL of 0.1 mol/L perchloric acid VS 
= 31.687 mg of $C_{19}H_{22}N_2.HCl$

Containers and storage Containers—Tight containers. 
Storage—Light-resistant.