

Calculate the amount, in $\mu\text{g}/\text{cm}^2$, of clonidine related compound B in the portion of the Transdermal System taken:

$$\text{Result} = CV/A$$

C = concentration of clonidine related compound B from the linear regression analysis ($\mu\text{g}/\text{mL}$)

V = volume of the *Sample solution* (mL)

A = area of the sample system (cm^2)

Acceptance criteria: NMT $10.0 \mu\text{g}/\text{cm}^2$

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in sealed, single-dose containers at a temperature not exceeding 30° .
- **LABELING:** The label states the total amount of clonidine in the Transdermal System and the release rate, in mg/day, for the duration of the application of one system. When more than one *Drug Release* test is given, the labeling states the *Drug Release* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** [\(11\)](#)

[USP Clonidine RS](#)

[USP Clonidine Related Compound B RS](#)

2-[(*E*)-2,6-Dichlorophenylimino]-1-(1-{2-[(*E*)-2,6-dichlorophenylimino]-imidazolidin-1-yl}-ethyl) imidazolidine.

$\text{C}_{20}\text{H}_{20}\text{Cl}_4\text{N}_6$ 486.23

¹ Viton O-rings or equivalent.

Page Information:

Not Applicable

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