

Analytical Profiles of Drug Substances, 7

## EPINEPHRINE

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193

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## CONTENTS

1. General Information
  - 1.1 Nomenclature
    - 1.11 Chemical Names
    - 1.12 Generic Name
    - 1.13 Trade Names
  - 1.2 Formula
    - 1.21 Empirical
    - 1.22 Structural and Stereochemical
  - 1.3 Molecular Weight
    - 1.31 Free Base
    - 1.32 Bitartrate
  - 1.4 Elemental Composition (base)
  - 1.5 Description
  - 1.6 Forms of Epinephrine Recognized in Official Compendia
2. Physical Properties
  - 2.1 Associated with the Solid State
    - 2.11 Crystallinity
    - 2.12 X-ray Diffraction
    - 2.13 Melting Point
  - 2.2 Solubility
  - 2.3 Spectral
    - 2.31 Ultraviolet
    - 2.32 Infrared
    - 2.33 Mass
    - 2.34 Optical Rotation and Dispersion
    - 2.35 NMR
  - 2.4 Distribution
3. Ionization in Aqueous Solution
4. Biochemical Considerations
5. Synthesis
6. Stability and Behavioral Chemistry
  - 6.1 Solid State
  - 6.2 Aqueous Solutions
    - 6.21 Racemization
    - 6.22 Reaction with Bisulfite
    - 6.23 Oxidation
    - 6.24 Miscellaneous Reactions
    - 6.25 Dosage Form Stability

7. Analytical Methods
  - 7.1 Fluorometric
  - 7.2 Colorimetric
  - 7.3 Polarimetric
  - 7.4 Titrimetric
  - 7.5 Chromatographic
    - 7.51 Thin-layer and Paper
    - 7.52 Gas Chromatography
    - 7.53 Liquid Column Chromatography
  - 7.6 Spectrophotometric
8. Acknowledgments
9. References

## 1. General Information

## 1.1 Nomenclature

## 1.11 Chemical Names

1- $\alpha$ -3,4-dihydroxyphenyl- $\beta$ -methylaminoethanol;  
 1-1-(3,4-dihydroxyphenyl)-2-methylaminoethanol; 3,4-dihydroxy  
 (1-hydroxy-2-methylaminoethyl)benzene; 1-methylaminoethanol-  
 catechol; 3,4-dihydroxy- $\alpha$ -(methylaminomethyl)benzyl alcohol;  
 (R)-(-)-3,4-Dihydroxy- $\alpha$ [(methylamino)methyl]benzyl alcohol;  
 4-[1-Hydroxy-2-(methylamino)ethyl]-1,2-benzendiol.

## 1.12 Generic Name

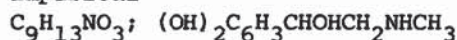
Epinephrine

## 1.13 Trade Names

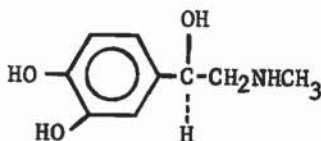
Many trade names (1) exist for this drug.  
 Some of the more commonly used trade names in the United  
 States are Adrenalin (Parke, Davis), Suprarenalin (Armour &  
 Co.), and Suprarenin (Sterling Drug, Inc.).

## 1.2 Formula

## 1.21 Empirical



## 1.22 Structural and Stereochemical



## 1.3 Molecular Weight

## 1.31 Free Base

183.21

## 1.32 Bitartrate (1:1 salt)

333.30 ( $\text{C}_9\text{H}_{13}\text{NO}_3 \cdot \text{C}_4\text{H}_6\text{O}_6$ )

## 1.4 Elemental Composition (base)

C 59%, H 7.1%, N 7.7%, O 26.2%

### 1.5 Description

The USP XIX (2) describes epinephrine as "white to nearly white, odorless, microcrystalline powder or granules, gradually darkening on exposure to light and air. With acids, it forms salts that are readily soluble in water, and the base may be recovered by the addition of ammonia water or alkali carbonates. Its solutions are alkaline to litmus."

### 1.6 Forms of Epinephrine Recognized in Official Compendia.

The USP XIX (3) contains epinephrine as the free base, the bitartrate salt, and the following formulations:

Formulation	Category
Epinephrine	Bronchodilator
Epinephrine Injection	Adrenergic
Epinephrine Nasal Solution	Adrenergic
Sterile Epinephrine Oil Susp.	Bronchodilator
Epinephrine Bitartrate Ophthalmic Solution	Adrenergic
Epinephrine Bitartrate for Ophthalmic Solution	Adrenergic

## 2. Physical Properties

### 2.1 Associated with the Solid State

#### 2.11 Crystallinity

Although epinephrine was the first hormone to be obtained in crystalline form, crystallographic information with regard to crystalline structure is not available. Winchell (4) describes epinephrine as colorless or light brown crystals or powder which darkens on exposure to air and quotes refractive indices as determined by Keenan (5) as being  $N_1 = 1.555$ ,  $N_2 = 1.733$

#### 2.12 X-ray Diffraction

Powder X-ray diffraction data (6) for epinephrine are given in Table 1.

#### 2.13 Melting Point

Kirk-Othmer (7) report the melting point of epinephrine as 211 - 212°C (215°C when heated rapidly).

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