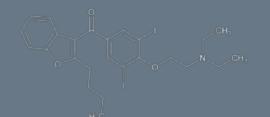
## Amiodarone Quality Solutions Category: Cardiovascular



Authorized Distributor

USP can support your development and manufacturing activities on Amiodarone-based medicines with these existing and upcoming standards.

## Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

| AMIODARONE HYDROCHLORIDE Official as of 01-Dec-2020 |                    |
|---|--------------------|
| USP Amiodarone Hydrochloride RS                     | <u>USP-1027302</u> |
| USP Amiodarone Related Compound D RS                | <u>USP-1027346</u> |
| USP Amiodarone Related Compound E RS                | <u>USP-1027357</u> |
| USP Amiodarone Related Compound H RS                | <u>USP-1027380</u> |

MONOGRAPH 4

## AMIODARONE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION Official as of 01-Dec-2016 USP Amiodarone Hydrochloride RS USP-1027302

MONOGRAPH 2

| AMIODARONE HYDROCHLORIDE INJE<br>Official as of 01-Jul-2021 | CTION              |
|---|--------------------|
| USP Amiodarone Hydrochloride RS                             | <u>USP-1027302</u> |
| USP Amiodarone Related Compound D RS                        | <u>USP-1027346</u> |
| USP Amiodarone Related Compound E RS                        | <u>USP-1027357</u> |
| USP Benzyl Alcohol RS                                       | <u>USP-1061901</u> |

| PHARMACEUTICAL ANALYTICAL IMPURITY(IES)* |                    |
|--|--------------------|
| USP Desiodoamiodarone PAI                | <u>USP-1A00720</u> |
| USP Desethylamiodarone PAI               | <u>USP-1A01080</u> |
| USP Monoiodoamiodarone PAI               | <u>USP-1A01090</u> |
| USP Methoxyamiodarone PAI I New          | <u>USP-1A00710</u> |

MONOGRAPH 3

| AMIODARONE HYDROCHLORIDE TAB<br>Official as of 01-Feb-2021 | LETS               |
|--|--------------------|
| USP Amiodarone Hydrochloride RS                            | <u>USP-1027302</u> |

<sup>\*</sup> Documents in PF Online are not official and not suitable to demonstrate compliance. They may never become official.

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01-Oct-2023. For publications related to **Amiodarone** in *PF* online after this date, please visit the integrated *USP-NF/PF* online.



<sup>\*</sup> Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.