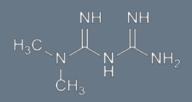
Metformin Quality Solutions

Category: Endocrine



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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

METFORMIN HYDROCHLORIDE Official as of 01-Nov-2020	
USP Melamine RS	<u>USP-1379183</u>
USP Metformin Hydrochloride RS	<u>USP-1396309</u>
USP Metformin Related Compound A RS	<u>USP-1396310</u>

MONOGRAPH 2

METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS Official as of 01-Apr-2022	
USP Metformin Hydrochloride RS	<u>USP-1396309</u>
USP Metformin Related Compound B RS	<u>USP-1396331</u>
USP Metformin Related Compound C RS	<u>USP-1396342</u>

MONOGRAPH 3

METFORMIN HYDROCHLORIDE TABLETS Official as of 01-May-2020	
USP Metformin Hydrochloride RS	<u>USP-1396309</u>

MONOGRAPH 4

PIOGLITAZONE AND METFORMIN HYE TABLETS Official as of 01-May-2020	DROCHLORIDE
USP Metformin Hydrochloride RS	<u>USP-1396309</u>
USP Pioglitazone Hydrochloride RS	<u>USP-1539905</u>

MONOGRAPH 5

GLYBURIDE AND METFORMIN HYDROCHLORIDE WTABLETS Official as of 01-Apr-2021	
USP Glyburide RS	<u>USP-1295505</u>
USP Glyburide Related Compound A RS	<u>USP-1295516</u>
USP Metformin Hydrochloride RS	<u>USP-1396309</u>
USP Metformin Related Compound B RS	<u>USP-1396331</u>
USP Metformin Related Compound C RS	<u>USP-1396342</u>

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

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MONOGRAPH 6

GLIPIZIDE AND METFORMIN HYDROCHLORIDE TABLETS Official as of 01-May-2020	
USP Glipizide RS	<u>USP-1292507</u>
USP Glipizide Related Compound A RS	<u>USP-1292609</u>
USP Metformin Hydrochloride RS	<u>USP-1396309</u>
USP Metformin Related Compound A RS	<u>USP-1396310</u>

Authorized Distributor

RELATED EXCIPIENTS STANDARDS

METHYLPARABEN SODIUM Official as of 01-Dec-2014	
USP Methylparaben RS	<u>USP-1432005</u>

RELATED EXCIPIENTS STANDARDS

METHYLPARABEN Official as of 01-May-2020	
USP Methylparaben RS	<u>USP-1432005</u>

* Documents in PF Online are not official and not suitable to demonstrate compliance. They may never become official.

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Official and Proposed Documentary Standards and Associated Physical Materials

RELATED EXCIPIENTS STANDARDS

DEXTROSE Official as of 01-May-2020	
USP Maltotriose RS	<u>USP-1375047</u>
USP Fructose RS	<u>USP-1286504</u>
USP Maltose Monohydrate RS	<u>USP-1375025</u>
USP Dextrose RS	<u>USP-1181302</u>

PHARMACEUTICAL ANALYTICAL IMPURITY(IES)*

NH

USP Guanylmelamine Dinitrate PAI I New

<u>USP-1A02890</u>

Authorized Distributor

RELATED EXCIPIENTS STANDARDS

PROPYLPARABEN Official as of 01-May-2020	
USP Propylparaben RS	<u>USP-1577008</u>
USP Ethylparaben RS	<u>USP-1267000</u>

RELATED EXCIPIENTS STANDARDS

PROPYLPARABEN SODIUM Official as of 01-Dec-2014	
USP Propylparaben RS	<u>USP-1577008</u>
USP Ethylparaben RS	<u>USP-1267000</u>

RELATED EXCIPIENTS STANDARDS

GLYCERIN Official as of 01-May-2020	
USP Diethylene Glycol RS	<u>USP-1193265</u>
USP Ethylene Glycol RS	<u>USP-1265515</u>
USP Glycerin RS	<u>USP-1295607</u>

RELATED EXCIPIENTS STANDARDS

TRIETHYL CITRATE Official as of 01-May-2023	
USP Triethyl Aconitate RS	<u>USP-1683537</u>
USP Triethyl Citrate RS	<u>USP-1683606</u>

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