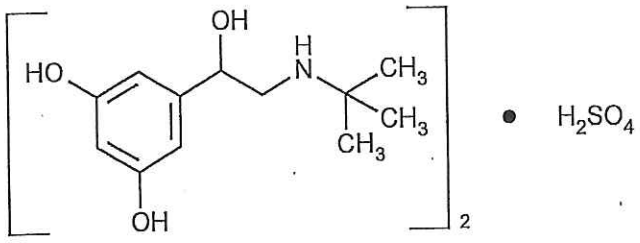
T32-1 T32-1

U.S. Pharmacopeia
The Standard of Quality℠

USP Certificate

Terbutaline Sulfate
LOT I0G250



Molecular Formula
$(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$

Molecular Weight
548.65

CAS Number
23031-32-5

LABEL TEXT

For use with specified USP-NF Tests. Not for use as a drug. Read MSDS before using.

USP REFERENCE STANDARD

TERBUTALINE SULFATE 125 mg

Do not dry. For quantitative applications, use a value of 0.995 mg of terbutaline sulfate per mg of material on the as is basis.
Keep container tightly closed.

CAT. NO. 1643500 USP ROCKVILLE, MD LOT I0G250

I0G250

USP certifies that the USP Reference Standards Committee, in accordance with their rules and procedures, determined that this USP Reference Standard lot is suitable to assess compliance with the monograph standards for which it is specified. The critical characteristics of this lot are usually determined independently in three or more laboratories, including USP, government, academic, and industrial collaborators.

QA Director

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
03 SEP 2018
TEL: 2726963 / 3544525/30
FAX: 2718073
P. O. BOX 29726 - 00202, NAIROBI

24-Sep-2007

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Calculation Value

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in USP or NF compendial applications for which the use of this Reference Standard is intended. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the Official USP Reference Standards catalog. In some cases, the previous lot may still be considered official. If so, it is identified in the column marked "Previous Lot/Valid Use Date." Ordinarily, the previous lot is carried in official status for about one year after the current lot enters distribution.

It is the responsibility of each user to determine that this lot is current when used. To ensure up-to-date information, USP publishes the Official USP Reference Standards Catalog, which contains official lot designations. This information is also available on the USP web site, at www.usp.org, as well as in the bimonthly subscription publication, *Pharmacopeial Forum*.

Instructions for Use

Follow the instructions in the appropriate USP or NF Monographs and General Requirements for Tests and Assays of the current *USP–NF*. In the event that instructions on the label of this lot differ from those found in the current *USP–NF*, those on the label supersede any instructions listed in Chapter <11>.

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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ISSUED

Johnson & Johnson

PW 10.5.017//8 Form A

CERTIFICATION OF SECONDARY REFERENCE STANDARD REPORT

Active Ingredient: Terbutalin Sulphate.

Primary reference standard details		Secondary reference standard details	
Name	Terbutalin Sulphate	Name	Terbutalin SO4
Supplier	USP	Lot number	1614000072
Lot number	IOG2SO ABS17-716	Location number	Q.C Dec 01
Location number	GLP	Retest date	Feb.2019
Expiry	N/A	Amount certified	100g
Stock before use	125mg	Container details: Amber glass jar	
Stock after use	49.8mg		
Traceability			
Handling instructions: N/A		Handling instructions: N/A	

Analytical details

Tick method type	HPLC ✓ GC UV Other (specify)
Method reference	~~0120052 Rev 4~~ 166840 Rev 2 (initialled 02-Mar-2018)
Method validated	N/A
Validation report number	N/A

Order new primary standard	YES ✓	NO
Reason for new primary standard	EXPIRED	EXHAUSTED ✓

Results

Specification	**98,0 – 102,0% (HPLC) 97,0 – 103,0% (GC)**
Specification if different from above	N/A
Potency	101.1
Potency acceptable	Yes
Purity Factor	N/A

Comments

N/A

Performer:(print)	Performer:(signature)	Title:(print)	Date:
S. Mhore	[signature]	Chemist	21.Feb.2018
Checked:(print)	**Checked:(signature)**	**Title:(print)**	**Date:**
Z. Mandudi	[signature]	Chemist	05 Mar 2018
Approved:(print)	**Approved:(signature)**	**Title:(print)**	**Date:**
S. Domingo	[signature]	QC Lead	05 Mar 2018