

Nock-WRS-Sg-12.

Getz Pharma (Private) Limited
Quality Control Department
Analytical Report (Working Standard)

WRS Sg-12

Reference Std.: 900001163 - SALBUTAMOL SULFATE (RS)
Reference: BP
Ref. Std. Batch No: 3784

Working Std.: 900001219 - SALBUTAMOL SULFATE (MICRONIZED)(WS)
Batch No.: WS-139052 Quantity: 60 G
Vendor Batch: SS/17007M3 Insp. Lot Date: 21.11.2017
Supplier: MELODY HEALTHCARE PVT. LTD. Date of Standardization: 21.11.2017
Manufacturer: MELODY HEALTHCARE PVT. LTD. No. of Vials: 10
Mfg Date: 01.04.2017 Expiry Date: 31.03.2020
Specification Ref. No.: WS-SAL-1219 Valid Upto.: 21.11.2018
Storage Condition: CRT

S. No.	Tests	Specification	Result	Ref. Method	Analyst
1	Appearance	White or almost white crystalline powder.	Complies	EP	JSIDDIQUI
2	Identification	The IR Spectrum of salbutamol sulfate sample should be concordant to that of the reference Standard.	Corresponds	EP	JSIDDIQUI
3	Loss on Drying	Not more than 0.50%	0.29 %	EP	JSIDDIQUI
4	Assay by Titration (AIB)	(97.51 - 100.90)%	100.16 %	EP	JSIDDIQUI
5	Assay by HPLC (AIB)	(97.51 - 100.90)%	99.58 %	BP	JSIDDIQUI
6	Assay by HPLC (ODB)	(98.00 - 101.00)%	99.87 %	BP	JSIDDIQUI
7	Related Substance Impurity D	Not more than 0.30%	0.00 %		JSIDDIQUI
8	Related Substance Impurity F	Not more than 0.30%	0.00 %	EP	JSIDDIQUI
9	Related Substance Impurity C	Not more than 0.20%	0.07 %	EP	JSIDDIQUI
10	Related Substance Impurity N	Not more than 0.20%	0.00 %	EP	JSIDDIQUI
11	Related Substance Impurity O	Not more than 0.20%	0.00 %	EP	JSIDDIQUI
12	Unspecified Impurities	Not more than 0.10%	0.00 %	EP	JSIDDIQUI
13	Total Impurities	Not more than 0.90%	0.07 %	EP	JSIDDIQUI

Remarks

The above working standard has been standardized against BP reference standard

Decision: Approved - W.S

Analyzed By: Juvariah Siddiqui
Date: 21.11.2017

Approved By: Abdullah Jabbar
Date: 21.11.2017



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