



WRS
S8-9



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SUPRIYA LIFESCIENCE LTD.

Certificate of analyses (Formerly known as Supriya Chemicals)
Working Standard

PRODUCT NAME	:	SALBUTAMOL/ALBUTEROL SULFATE	A.R. NUMBER	:	SLL/QC/FP/15/0743
BATCH NUMBER	:	SLL/SS/0815067	MFG.DATE	:	Aug.2015
WSTD NUMBER	:	SLL/WS/SS/15/009	DATE OF ANALYSIS	:	11/09/2015
DATE OF PREPARATION	:	11/09/2015	QTY. PREPARED	:	14.0 g
USE BEFORE	:	10/09/2016	RETEST DATE	:	10/09/2016

S. No.	Test	Specifications	Results
1.	Appearance	White or almost white, crystalline powder.	A white crystalline powder.
2.	Identification by IR Absorption	The IR absorption spectrum should be concordant with that of Salbutamol Sulfate reference standard.	Positive
3.	Related substances by HPLC (%)		
	i. Impurity D	Not more than 0.3	BDL
	ii. Impurity F	Not more than 0.3	BDL
	iii. Impurity C	Not more than 0.2	0.14
	iv. Impurity N	Not more than 0.2	BDL
	v. Impurity O	Not more than 0.2	BDL
	vi. Unspecified impurity	Not more than 0.10	0.05
	vii. Total impurities	Not more than 0.9	0.19
4.	Chromatographic purity by TLC	Any spot, other than the principal spot, obtained from the sample solution is not greater in size and intensity than the spot produced by the standard solution (0.5%) and sum of the impurities is not greater than 2.0%	Positive
5.	Loss on drying @105°C (% w/w)	Not more than 0.5	0.17
6.	Water by KF (% w/w)	Not more than 0.5	0.16
7.	Assay on anhydrous basis (% w/w) by HPLC	98.5 to 101.0	99.67

Remark: Salbutamol Sulfate / Albuterol Sulfate complies with respect to above mentioned test as per IP/BP/EP/USP specification.

Analysed By:
Date: 21/02/16

Reviewed By:
Date: 21/02/16

Approved by:
Date: 21/02/16

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