WRS
R11-2

CADILA PHARMACEUTICALS LIMITED

1389, Trasad Road,
Dholka-387810,
Dist.: Ahmedabad (INDIA)

Annexure-V

Quality Control Department

ANALYTICAL REPORT – WORKING STANDARD

(Ref SOP No.: DQC309)

Name : Rupatadine Fumarate **Working std. Lot No.** : QC/WS/RUPA-IH/01/15

Date of Analysis : 26/06/2015 **Method Reference** : IH

Effective Date : 29/06/2015 **Valid upto** : 28/06/2017

API Batch No. : 2RU003

Name of Manufacturer : Cadila Pharmaceuticals ltd

Evaluated against: Standard B. No. WRS/RUP/004

TESTS	RESULTS	SPECIFICATIONS
1. Appearance	Slightly pink colour powder.	White to slightly pink colour powder.
2. Identification	A: Positive	A: By HPLC In the Assay, the retention time of the major peak in the chromatogram obtained with assay preparation should correspond to that of the major peak in the chromatogram obtained with standard preparation.
	B: Positive	B: By Infra-red absorption: The infra-red absorption spectrum of the substance being examined in potassium bromide dispersion should be concordant with the spectrum obtained from similar preparation with the spectrum of Rupatadine Fumarate standard.
3. Loss on drying.	0.3 % w/w	Not more than 0.50 % w/w
4. Assay	100.0 % w/w as is basis. 100.3 % w/w on dried basis.	It should contain not less than 98.0 % w/w and not more than 102.0 % w/w, calculated on dried basis.

The product complies / ~~does not comply~~ with the above specifications.

Remark: Store in well-closed airtight container, flush with nitrogen, protected from light at ambient temperature.

Prepared By: Amol 29/06/15 **Checked By:** 29/06/15 **Approved By:** 29/06/15

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