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Rallis India Limited
Central Quality Assurance Laboratory
DAHEJ

Hexaconazole HPLC Ext Std Method Validation Report

Sr. No.	Type of test/characteristics		Minimum requirement for Assay of Active Ingredient	Validation Results
1	**Specificity**		Absence of interference peaks. No elution of any impurity peak at the retention of Internal Standard and Active Ingredient.	No interference of impurity peak(s) at the RT of Internal Standards and Product peaks.
2	**Linearity over the 80% - 120% of working concentration.**	**Correlation Coefficient**	≥ 0.99	0.9993
3	**Range**	**80% - 120% of working concentration.**	0.0800 gm - 0.1200 gm	0.0801 - 0.1204
4	**Repeatability (Injection Precision)**	**% RSD**	1.0 Max.	0.3
5	**Reproducibility (Method Precision)**	**% RSD**	1.0 Max.	0.37
6	**Accuracy**	**% Accuracy for Active Ingredient ≤ 10 %**	98.0 - 102.0	100.8
7	**Ruggedness**			
	a) Different Analyst	**Linearity - Correlation Coefficient**	≥ 0.99	0.9998
	b) Different Instrument	**% Accuracy**	98.0 - 102.0	100.0
8	**Robustness**			
a)	**Variation in Flow Rate from 1.0 to 0.8 ml/min.**	**Linearity - Correlation Coefficient**	≥ 0.99	0.9979
b)	**Variation in mobile phase (ACN: Water: Methanol) from 70:20:10 to 65:25:10**	**Linearity - Correlation Coefficient**	≥ 0.99	0.9991
c)	**Variation in wavelength 230± 2 nm**			
	i) at 228 nm	**Linearity - Correlation Coefficient**	≥ 0.99	0.9992
	ii) at 232 nm	**Linearity - Correlation Coefficient**	≥ 0.99	0.9992

Conclusion - Method is validated as per the guidelines and found complying with the requirements for analysis of Assay of Hexaconazole tech, Hexaconazole WDG, Hexaconazole EC, Hexaconazole SC and Hexaconazole secondary standard.

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