

121RS-A3S-3



CERTIFICATE OF ANALYSIS

WORKING STANDARD

Material	Azelastine Hydrochloride Ph.Eur	A.R.No	072RIF1986
Evaluated against	EPCRS	LOT No./ Batch No/ Code No.	1.0 RS.No.RS08049
Mfg. Date for Material	01.07.2013	Exp. date for Material	31.07.2018
Reference	Spec No.BD0037P0DA Rev No.1.0	WS No	WS15045
Effective Date	22.04.2015	Use before Date	22.04.2016
Quantity prepared	45.0 gm	No. of container Prepared	24
Intended Use	For Qualitative and Quantitative Analysis	Direction for Use	As such
TEST	RESULTS	SPECIFICATION	Hard book No., Page No., Template Issuance No.
➤ Description	White crystalline powder.	White or almost white, crystalline powder.	T.I.No.-MR15/1068 Page no.01
➤ Identification IR	Meets the requirements	The infrared (IR) absorption spectrum of the sample as potassium bromide dispersion Should be concordant with that of similarly recorded IR spectrum of Azelastine Hydrochloride Reference Standard .	T.I.No.-MR15/1068 Page no.03
➤ Loss on drying	0.20%	Not more than 0.5 %	T.I.No.-MR15/1068 Page no.18
➤ Related substances	BQL BQL BQL BQL BQL BQL BQL BQL	Method I a) Impurity A: NMT 0.10 % b) Impurity B: NMT 0.10 % c) Impurity C: NMT 0.10 % d) Impurity D: NMT 0.10 % e) Impurity E: NMT 0.10 % f) Any other Impurity: NMT 0.10% Method II Azelastine HCl isomer :NMT 0.10 % Total of all Impurities :NMT 0.20%	T.I.No.-MR15/1068 Page no.05 T.I.No.-MR15/1068 Page no.13
➤ Assay (as is basis) (on dried basis)	100.1%* 100.3%	Not less than 99.0 % and not more than 101.0 % on dried basis.	T.I.No.-MR15/1068 Page no.21
Remarks: The material complies against the Reference standard and qualifies for usage as a working standard.			
Storage: Store in well-closed container protected from light, at a temperature between 2°C to 8°C, preferably store in refrigerator.			
*Note: Take a value of 100.0% during calculation			
Analyzed by / Date <i>Man</i> 22/04/15		Checked by / Date <i>P</i> 22/04/15	
Approved by / Date <i>P</i> 22/04/15			

F/QCS-023/009/00

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