Hangzhou Huarong Pharm Co.,Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.
TEL: 0086-571-86758373 FAX: 0086-571-81131109

Certificate of Analysis

Product	Beclometasone Dipropionate,Anhydrous		
Batch No.	Z11-230301-m4	Batch Size	5.16kg
Package	/	Delivered Quantity	/
Mfg. Date	04-08-2022	Analysis Date	20-03-2023
Retest Date	03-08-2025	Report Date	20-03-2023
Reference	Ph. Eur.8.0		

Item	Specification	Result
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification	A.Conforms to the CRS spectrum.	Conforms
	B. The solution gives reaction of chlorides	Conforms
	C. Loss on drying≤0.5%	Conforms
Specific optical rotation	+108~+115(dried substance)	+109.0
Related substances（by HPLC）	Impurity A（RRT about 0.3）≤0.2%	Undetected
	Impurity B（RRT about 0.6）≤0.5%	Undetected
	Impurity C（RRT about 1.8）≤0.15%	Undetected
	Impurity D（RRT about 1.1）≤0.2%	Undetected
	Impurity F（RRT about 2.2）≤0.5%	Undetected
	Impurity L（RRT about 1.3）≤0.6%	0.03%
	Impurity M（RRT about 1.2）≤0.5%	Undetected
	Impurity N（RRT about 2.0）≤0.2%	Undetected
	Unspecified impurities≤0.10%	Undetected
	Total impurities≤1.3%	0.03%
Loss on drying	≤0.5%	0.2%
Assay (by HPLC)	Contains 96.0% to 102.0% of $C_{28}H_{37}ClO_7$, calculated on dried basis	99.4%
Residual solvents	Ethanol≤5000ppm(LOD:5ppm)	98ppm
	Methylene chloride≤600ppm(LOD:6ppm)	Undetected
	Hexane≤290ppm(LOD:3ppm)	Undetected
	Dioxane≤380ppm(LOD:4ppm)	Undetected
	Pyridine≤200ppm(LOD:2ppm)	Undetected
Conclusion:	Meet the specification according to Ph. Eur.8.0	

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