

Clobetasol propionate

CODE ARTICLE: 94200	BATCH: 0124191	Active pharmaceutical ingredient
TEST DATE: 23/10/2023	TEST: QC-00257835	
EXPIRY DATE: 30/05/2028	FABRICATION DATE: 30/06/2023	MR: 467,00
CAS: [25122-46-7]	FORMULA: C25H32ClFO5	
SYNONYMS / BOTANICAL NAME: 17-Propionato de clobetasol		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			WHITE OR ALMOST WHITE CRYSTAL POWDER	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN ACETONE				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN ETHANOL				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
SPECIFIC ROTATION	115 DEGREES		112	118	PH.EUR.*
<u>RELATED SUBSTANCES (HPLC)</u>					
TOTAL IMPURITIES	0,3 %			<=1,0	PH.EUR.*
UNSPECIFIED IMPURITIES	0,06 %			<=0,10	PH.EUR.*
IMPURITY A	<RT=0,05 %			<=0,2	PH.EUR.*
IMPURITY B	0,2 %			<=0,3	PH.EUR.*
IMPURITY D	<RT=0,05 %			<=0,2	PH.EUR.*
IMPURITY E	N.D. %			<=0,3	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	0,5	PH.EUR.*
SULPHATED ASHES	0,04 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,3 %		97	102	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	94,55			3000	Manufacture's Standard
METHYLENE CHLORIDE	N.D.			600	Manufacture's Standard
ACETONE	N.D.			5000	Manufacture's Standard
ETHYL ACETATE	N.D.			5000	Manufacture's Standard
DIMETHYL FORMAMIDE	N.D.			880	Manufacture's Standard
PYRIDINE	N.D.			200	Manufacture's Standard
PARTICLE SIZE	CONFORM			<20micras 100%	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 54540 G. P. E. PVT. LTD. (India) Manufacturer Batch: APL/CLP/06038/H-23 Manufacturer original CoA available under request

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TEST	RESULTS	Units	MIN	MAX	METHOD
Risk Assessment Evaluation for Nitrosamines	CONFORM				



Silvia Sancho-Tello Ripoll
Technical Director.

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