METAPHARMACEUTICAL IND SL
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LOSARTAN POTASSIUM (EUR. PH.)

PRODUCT CODE: 8355113	CAS Nº: 124750-99-8	ANALYSIS Nº: 207/24	
MANUFACTURER BATCH:	10131-240501	CERTIFICATE ID:	43.175
SUPPLIER BATCH:	----	MANUFACTURING DATE:	17/05/2024
METAPH BATCH:	0020824	RETEST DATE:	16/05/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder, hygroscopic	White crystalline powder, hygroscopic
Identification A	Complies	Complies
Identification B	Complies	Complies
Related substances		
Impurity D	<= 0.15 %	Not Detected
Impurity J	<= 0.15 %	Not Detected
Impurity K	<= 0.15 %	Not Detected
Impurity L	<= 0.15 %	Not Detected
Impurity M	<= 0.15 %	Not Detected
Unspecified impurities	<= 0.10 %	0.06 % (RT = 22.55 min)
Total impurities	<= 0.3 %	0.06 %
Loss on drying	<= 0.5 %	0.2 %
Assay	98.5 - 101.5 %	100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Losartan Potassium is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed, in a cool, dry place.

Analysis date: 22/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001485