

Certificate of Analysis No. 01/25/LT/Armila/K

Product: PROCAINE HYDROCHLORIDE

Batch No.: 2404056

Quantity: 1 x 100 g

Producer: CHONGQING SOUTHWEST

Methods of analysis: Ph. Eur. 11.0 (01:2017:0050)

Expiry date: 24.04.2028


Results of analysis:

Parameter		Specification	Result
Characters		A white or almost white, crystalline powder or colourless crystals, very soluble in water, soluble in ethanol (96 per cent).	Confirmed
Identification	A. Melting point [°C]	154 – 158	155.1
	B. IR absorption	Positive	Confirmed
	C. Colour reaction	Positive	Confirmed
	D. Colour discharged reaction	Positive	Confirmed
	E. Reaction of chlorides	Positive	Confirmed
	F. Primary aromatic amines reaction	Positive	Confirmed

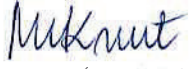
Decision:

This batch of pharmaceutical raw material meets/does not meet the requirements of Ph. Eur. 11.0*

Check
(Laboratory Manager):

Z-ca Kierownika Laboratorium

mgr Grzegorz Piątek

Accept
(Quality Manager):

Kierownik Kontroli Jakości

mgr inż. Katarzyna Mikiut

* cross out needless

Certificate of Analysis No. 01/25/LT/Armila

Product: PROCAINE HYDROCHLORIDE

Batch No.: 2404056

Quantity: 50.0 kg

Producer: CHONGQING SOUTHWEST

Methods of analysis: Ph. Eur. 11.0 (01:2017:0050)

Expiry date: 24.04.2028

Results of analysis:

Parameter		Specification	Result
Characters		A white or almost white, crystalline powder or colourless crystals, very soluble in water, soluble in ethanol (96 per cent).	Confirmed
Identification	A. Melting point [°C]	154 – 158	155.3
	B. IR absorption	Positive	Confirmed
	C. Colour reaction	Positive	Confirmed
	D. Colour discharged reaction	Positive	Confirmed
	E. Reaction of chlorides	Positive	Confirmed
	F. Primary aromatic amines reaction	Positive	Confirmed
Tests	Appearance of solution	Solution S is clear and colourless	Confirmed
	pH	5.0 – 6.5	5.4
	Related substances	Complies	Confirmed
	Loss on drying [%]	≤ 0.5	0.0
	Sulphated ash [%]	≤ 0.1	0.03
Assay [%]		99.0 – 101.0	100,7

Decision:

This batch of pharmaceutical raw material meets/~~does not meet~~ the requirements of Ph. Eur. 11.0*

Check
(Laboratory Manager):

Z-ca Kierownika Laboratorium

mgr Grzegorz Piatek

Accept
(Quality Manager):

Kierownik Kontroli Jakości

mgr Inż. Katarzyna Mikrut

* cross out needless