

CAFFEINE ANHYDROUS EP/USP GRANULAR FORM

PRODUCT SPECIFICATIONS

Test	Method	Limit
1. Organoleptic	inspection	white granules with no off odor
2. Identification	EP: 0267 / IR spectrum	conform to standard
3. Appearance of 1% w/v Solution	EP	clear and colourless
4. Acidity	EP	<0.2ml NaOH 0.01M
5. Melting point	USP	235 - 239 °C
6. Related substances (TLC)	EP	<0.50% w/w
7. Chromatographic purity (HPLC)	USP	<0.1% each and total
8. Other alkaloids	USP	no precipitate is formed
9. Sulphates	EP	<500ppm
10. Heavy metals (as Pb)	EP	<10 ppm
11. Readily carbonizable substances	USP <271>	no darker color than m.f.D
12. Organic Volatile Impurities	USP <467> I	CH ₂ Cl ₂ <1ppm
13. Loss on drying	EP	<0.50% w/w
14. Sulphated ash	EP	<0.10% w/w
15. Assay	EP: 0267	98.5 - 101%
16. Granulometry	2.8 mm test	5% max above sieve

Stabilimento Cav.G.Testa SpA.
Albenga.