

Certificate of Analysis

Productname: Codeini phosphas hemihydr.(90)
Number of analysis/Inspection Code: 1 / KEUR-198441B
Batchnumber: 23J04-F05-385493
Reference code / No.: 3960 / 5170923
Analysed according to: PHEUR11.2+

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------|---|---------|------|-----------------|
| Appearance | Fine, (almost) white powder or small colorless crystals | Conform | | |
| Particle size | 97% < 90 µm | Conform | | |
| Identification A | Conform | Conform | | IR-spectrum |
| Identification D | 1,5 - 3,0 | 2,2 | | Loss on drying |
| Identification E | Conform | Conform | | Phosphate |
| pH | 4,0 - 5,0 | 4,5 | | 4%m/V |
| Specific optical rotation | -102 - -98 | -101 | | 2%m/V; dried |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=1,0 | 0,2 | % | |
| Impurity H | <=0,25 | <0,05 | % | |
| Impurity C | <=0,2 | <0,05 | % | |
| Impurity D | <=0,2 | <0,05 | % | |
| Impurity E | <=0,2 | <0,05 | % | |
| Impurity B | <=0,15 | <0,05 | % | |
| Impurity F | <=0,15 | <0,05 | % | |
| Impurity G | <=0,15 | <0,05 | % | |
| Impurity I | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,06 | % | |
| Total impurities | <=1,5 | 0,3 | % | |
| Sulphates | <=0,1 | <0,1 | % | |
| Loss on drying | 1,5 - 3,0 | 2,2 | % | 105°C |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | Data producer |
| Assay Codeini phosph. hemih. | 99,0 - 101,0 | 99,9 | %m/m | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Saneca Pharmaceuticals a.s. / SK
CEP :

Release:
Anthony Amoureux
Qualified Person

11/23/23

Expiration: 31-08-28

Conclusion: APPROVED

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